

Sekcja

1

1. Deklaracja zgodności

Dokumentacja techniczna Systemy shaverów i zasilania

Kody GMDN Pełną listę wszystkich kodów GMDN, o których mowa w niniejszej dokumentacji technicznej, można znaleźć w Wykazie Kor. 36

Korekta 36

Klasa MDD, Reguła Klasa IIa, Reguła 6 oraz Reguła 9

Ścieżka zgodności Załącznik II (z wyłączeniem Sekcji 4)

**Jednostka Notyfikowana/
Numer** BSI / CE 2797
(poprzednio BSI / CE 0086)

Producent Arthrex, Inc.
1370 Creekside Boulevard
Naples, FL 34108 USA

Przedstawiciel w WE Arthrex GmbH
Erwin-Hielscher-Strasse 9
81249 Monachium, Niemcy

1.1. Oświadczenie do Deklaracji Zgodności

Niżej podpisany oświadcza, że wymienione powyżej urządzenia medyczne są zgodne z odpowiednimi sekcjami dyrektywy dotyczącej urządzeń medycznych 93/42/EWG.

Ganga Kolli
Ganga Kolli (Jun 6, 2024 10:37 EDT)

Ganga Kolli,
Senior Manager, Dział Regulacji UE

Data

1.2. Lista urządzeń według numeru katalogowego

Lista urządzeń według numerów katalogowych znajduje się w części B.

Section

1

1. Declaration of Conformity

Technical File Shaver and Power Systems

GMDN Codes Refer to Parts List Rev. 36 for a complete list of all GMDN Codes subject of this technical file

Revision 36

MDD Class, Rule Class IIa, Rule 6 and Rule 9

Route of Compliance Annex II (excluding Section 4)

Notified Body / Number BSI / CE 2797
(Formerly - BSI / CE 0086)

Manufacturer Arthrex, Inc.
1370 Creekside Boulevard
Naples, FL 34108 USA

EC Representative Arthrex GmbH
Erwin-Hielscher-Strasse 9
81249 München Germany

1.1. Conformity Declaration Statement

The undersigned hereby declares that the medical devices specified above conform to relevant sections of the Medical Device Directive 93/42/EEC.

Ganga Kolli

Ganga Kolli (Jun 6, 2024 10:37 EDT)

Ganga Kolli
Senior Manager, EU Regulatory Affairs

Date

1.2. List of Devices by Catalog Number

The *List of Devices by Catalog Number* is in Part B.

Manufacturer name:	Manufacturing location:	EC QA Cert. number:	Product Code:	Product Name:	Portfolio / PROFIT CENTER	Include in MDR Submission? ("N/A- new MDR submission" means the device is a new addition and has no previous MDD certificate)	Class:	GMDN Code:	TF	Rule:	Annex:	First DoC
Arthrex, Inc.	Naples, FL	CE 85507	AR-1250LSR	Arthrex 3mm SutureTak ShaverDrill (Multi Pack)			IIa	36224	Shaver and Power Systems	6	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-1250LSR-1	Arthrex 3mm SutureTak ShaverDrill (Single Pack)			IIa	36224	Shaver and Power Systems	6	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-1821	SAW BLADE, HALL STYLE, 7MM DEPTH STOP			IIa	43376	Shaver and Power Systems	6	II	4/1/1999
Arthrex, Inc.	Naples, FL	CE 85507	AR-1825	SAW BLADE, SYNTHES WITH DEPTH STOP			IIa	43376	Shaver and Power Systems	6	II	4/1/1999
Arthrex, Inc.	Naples, FL	CE 85507	AR-1825L	SAW BLADE, SYNTHES 60 X 27 MM			IIa	43376	Shaver and Power Systems	6	II	2/1/2000
Arthrex, Inc.	Naples, FL	CE 85507	AR-1827	SAW BLADE, STRYKER STYLE 7MM DEPTH STOP			IIa	43376	Shaver and Power Systems	6	II	5/1/1999
Arthrex, Inc.	Naples, FL	CE 85507	AR-1827S	GRAFT HARVESTING KIT, STRYKER STYLE			IIa	44093	Shaver and Power Systems	6	II	11/15/2004
Arthrex, Inc.	Naples, FL	CE 85507	AR-1831	SAW BLADE, ARTHREX STYLE			IIa	43376	Shaver and Power Systems	6	II	1/1/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-1934DSK	ShaverDrill™ Disposables Kit for SutureTak® AnchorNull			IIa	43390	Shaver and Power Systems	6	II	6/16/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-1938DSR	3.0 mm Knotless SutureTak® ShaverDrill™ Device, Hard Bone			IIa	44093	Shaver and Power Systems	6	II	6/16/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-1938DSK	ShaverDrill™ Disposables Kit for Knotless SutureTak® Anchor Hard Bone			IIa	43390	Shaver and Power Systems	6	II	6/16/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-200	DRILLSAW HIGHSPEED 200			IIa	66243	Shaver and Power Systems	6	II	8/2/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-200C	ARTHREX AR-200 CONSOLE			IIa	66243	Shaver and Power Systems	6	II	8/2/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-200CA	CANNULATED ADAPTER for AR-200			IIa	66243	Shaver and Power Systems	6	II	8/2/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-200H	HANDLE FOR AR-200			IIa	66243	Shaver and Power Systems	6	II	8/2/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-200M	MOTOR WITH CABLE 3.5M			IIa	66243	Shaver and Power Systems	6	II	8/2/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-200M-ISO	MOTOR W. CABLE 3.5M, ISO COUPLING			IIa	66243	Shaver and Power Systems	6	II	8/2/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-200SP	SPRAYCLIP FOR AR-200			IIa	66243	Shaver and Power Systems	6	II	8/2/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-2922DSR-24	ShaverDrill™ for 2.4 mm PushLock®			IIa	43390	Shaver and Power Systems	6	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-2922DSR-24	ShaverDrill™ for 2.4 mm PushLock® Anchor, Hard Bone			IIa	43390	Shaver and Power Systems	6	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-2923DSR	Arthrex 2.9 PushLock ShaverDrill (Multi Pack)			IIa	36224	Shaver and Power Systems	6	II	1/14/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-2923DSR-1	Arthrex 2.9 PushLock ShaverDrill (Single Pack)			IIa	36224	Shaver and Power Systems	6	II	4/6/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-2923DSK	ShaverDrill™ Disposables Kit for Short 2.9 mm PushLock® Anchor			IIa	43390	Shaver and Power Systems	6	II	6/16/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-2923DSK-1	ShaverDrill™ Disposables Kit for Short 2.9 mm PushLock® Anchor			IIa	43390	Shaver and Power Systems	6	II	6/16/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-2923DTSK	ShaverDrill™ Disposables Kit for Short 2.9 mm PushLock® AnchorHard Bone			IIa	43390	Shaver and Power Systems	6	II	6/16/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-2923DTSK-1	ShaverDrill™ Disposables Kit for Short 2.9 mm PushLock® AnchorHard Bone			IIa	43390	Shaver and Power Systems	6	II	6/16/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-2923DTSR	Short 2.9 mm PushLock® ShaverDrill™ Device, Hard Bone			IIa	44093	Shaver and Power Systems	6	II	6/16/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-300	Arthrex AR-300 Handpiece			IIa	66243	Shaver and Power Systems	9	II	11/4/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300/600	Charging Station for AR-300/AR-600 Batteries			IIa	66243	Shaver and Power Systems	9	II	8/31/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300/600F-AUS	Flex for AR-300/600 - Australia			IIa	14147	Shaver and Power Systems	9	II	11/4/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300/600F-BR	Flex for AR-300/600 - Brazil			IIa	14147	Shaver and Power Systems	9	II	11/4/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300/600F-CH	Flex for AR-300/600 - Switzerland			IIa	14147	Shaver and Power Systems	9	II	11/4/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300/600F-DK	Flex for AR-300/600 - Denmark			IIa	14147	Shaver and Power Systems	9	II	11/4/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300/600F-EU	Flex for AR-300/600 - Europe			IIa	14147	Shaver and Power Systems	9	II	11/4/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300/600F-UK	Flex for AR-300/600 - United Kingdom			IIa	14147	Shaver and Power Systems	9	II	11/4/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-040S	300 SAGITTAL SAW BLADE 40X14X0.6 mm			IIa	43376	Shaver and Power Systems	6	II	5/29/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-041S	300 SAGITTAL SAW BLADE 40X9.5X0.6 mm			IIa	43376	Shaver and Power Systems	6	II	5/29/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-042S	Sagittal Saw Blade for Arthrex 300 25 x 9.4 x 0.7 mm			IIa	43376	Shaver and Power Systems	6	II	4/6/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-043S	300 SAGITTAL SAW BLADE 25X9.4X0.6			IIa	43376	Shaver and Power Systems	6	II	2/2/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-044S	300 SAGITTAL SAW BLADE 25X5.5X0.6 mm			IIa	43376	Shaver and Power Systems	6	II	5/29/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-045S	300 SAGITTAL SAW BLADE 16X5.5X0.6 mm			IIa	43376	Shaver and Power Systems	6	II	5/29/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-050S	300 RECIPROCATING SAW BLADE 15 x 6 x 0.6 mm			IIa	45493	Shaver and Power Systems	6	II	1/21/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-051S	300 RECIPROCATING SAW BLADE 25 x 6 x 0.6 mm			IIa	45493	Shaver and Power Systems	6	II	1/21/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-052S	300 RECIPROCATING SAW BLADE 40 x 6 x 0.6 mm			IIa	45493	Shaver and Power Systems	6	II	1/21/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-400S	300 SAGITTAL BLADE STERILE 41 X 9.4 X .60MM			IIa	43376	Shaver and Power Systems	6	II	2/3/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-400-SI	300 SAGITTAL SAW BLADE, 41 X 14 X .60MM			IIa	43376	Shaver and Power Systems	6	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-401S	300 SAGITTAL BLADE STERILE 41 X 9.4 X .55MM			IIa	43376	Shaver and Power Systems	6	II	2/3/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-401-SI	300 SAGITTAL SAW BLADE, 41 X 9.4 X .55MM			IIa	43376	Shaver and Power Systems	6	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-402S	300 SAGITTAL BLADE STERILE 25 X 9.4 X .60MM			IIa	43376	Shaver and Power Systems	6	II	2/3/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-402-SI	300 SAGITTAL SAW BLADE, 25 X 9.4 X .60MM			IIa	43376	Shaver and Power Systems	6	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-403S	300 SAGITTAL BLADE STERILE 25 X 9.4 X .55MM			IIa	43376	Shaver and Power Systems	6	II	2/3/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-403-SI	300 SAGITTAL SAW BLADE, 25 X 9.4 X .55MM			IIa	43376	Shaver and Power Systems	6	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-404S	300 SAGITTAL BLADE STERILE 25 X 5.5 X .60MM			IIa	43376	Shaver and Power Systems	6	II	2/3/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-404-SI	300 SAGITTAL SAW BLADE, 25 X 5.5 X .60MM			IIa	43376	Shaver and Power Systems	6	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-405S	300 SAGITTAL BLADE STERILE 16 X 5.5 X .55MM			IIa	43376	Shaver and Power Systems	6	II	2/3/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-405-SI	300 SAGITTAL SAW BLADE, 16 X 5.5 X .55MM			IIa	43376	Shaver and Power Systems	6	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-406S	300 SAG BLD, STRL 17 X 9.4 X .55 WITH STOP			IIa	43376	Shaver and Power Systems	6	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-407S	SAW BLADE, 300 SAGITTAL, 18.5 x 10 x .55 MM			IIa	43376	Shaver and Power Systems	6	II	5/31/2011
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-408S	SAW BLADE, 300 SAGITTAL, 12 x 5.5 x .55 MM			IIa	43376	Shaver and Power Systems	6	II	5/31/2011
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-450S	300 SAGITTAL SAW BLADE, ANGLED 19 x 10 x 0.6MM			IIa	46476	Shaver and Power Systems	6	II	2/9/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-500S	300 RECIP BLADE STERILE 15 X 5.5 X .60MM			IIa	45493	Shaver and Power Systems	6	II	2/3/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-500-SI	300 RECIP SAGITTAL SAW 15 X 5.5 X .60MM			IIa	45493	Shaver and Power Systems	6	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-501S	300 RECIP BLADE STERILE 25 X 5.5 X .60MM			IIa	45493	Shaver and Power Systems	6	II	2/3/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-501-SI	300 RECIP SAGITTAL SAW 25 X .60MM			IIa	45493	Shaver and Power Systems	6	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-502S	300 RECIP BLADE STERILE 40 X 6.0 X .60MM			IIa	45493	Shaver and Power Systems	6	II	2/3/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-502-SI	300 RECIP SAGITTAL SAW 40 X .60MM			IIa	45493	Shaver and Power Systems	6	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-300ATK	Aseptic Transfer Kit for AR-300			IIa	66243	Shaver and Power Systems	9	II	8/31/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300B	Burr Attachment 2.35 mm			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-8001	Burr, straight, 13.0 mm, diam. 2.0 mm			IIa	45553	Shaver and Power Systems	6	II	1/21/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-8002	BURR, STRAIGHT 8 MM, DIA. 2 MM			IIa	45553	Shaver and Power Systems	6	II	1/21/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-8003	BURR, STRAIGHT 12 MM, DIA. 2.2 MM			IIa	45553	Shaver and Power Systems	6	II	1/21/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-8004	BURR, CONICAL 12 MM, DIA. 2.2 MM			IIa	45553	Shaver and Power Systems	6	II	1/21/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-8101	Burr, conical, 13.0 mm, diam. 2.9 mm			IIa	45553	Shaver and Power Systems	6	II	2/2/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-8102	BURR, STRAIGHT 13 MM, DIA. 2.9 MM			IIa	45553	Shaver and Power Systems	6	II	1/21/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-8103	BURR, OVAL 15 MM, DIA. 5 MM			IIa	45553	Shaver and Power Systems	6	II	1/21/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-300B-2	Drill Attachment for Ø2.35 and 2750rpm			IIa	43962	Shaver and Power Systems	6	II	4/8/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-8201	Burr, straight, 19.5 mm, diam. 2.0 mm			IIa	45553	Shaver and Power Systems	6	II	2/2/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-8202	BURR, STRAIGHT 20 MM, DIA. 3.1 MM			IIa	45553	Shaver and Power Systems	6	II	1/21/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-300CA	Cannulated Adapter			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300D40-1	Drill Attachment - Style A0 1300rpm			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300D40-2	Drill Attachment - Style A0 2700rpm			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300D1	Drill Jacobs Chuck 0-4.0 mm			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300D1H	Drill Jacobs Chuck Hybrid 0-5.0 mm			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300DK30	Drill Keyless Chuck 0-3.0 mm			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300DK45	Drill Keyless Chuck 2.0-4.5 mm			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300H	Elongation Handle			IIa	47829	Shaver and Power Systems	1	VII	9/13/2016

Manufacturer name	Manufacturing location	EC QA Cert. number:	Product Code:	Product Name:	Portfolio / PROFIT CENTER	Include in MDR Submission? ("N/A- new MDR submission" means the device is a new addition and has no previous MDD certificate)	Class:	GMDN Code:	TF	Rule:	Annex:	First DoC
Arthrex, Inc.	Naples, FL	CE 85507	AR-300HKEY	Replacement Key for Hybrid Chuck for AR-300			IIa	44605	Shaver and Power Systems	6	II	12/6/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-300KEY	Replacement Key for Jacobs Chuck for AR-300			IIa	44605	Shaver and Power Systems	6	II	12/6/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-300L	Battery Pack for AR-300 Li-Ion			IIa	66243	Shaver and Power Systems	9	II	8/31/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300LBH	Li-Ion Battery Housing for AR-300			IIa	66243	Shaver and Power Systems	9	II	8/31/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300PD24	Pin Driver Attachment 1.0-2.4 mm			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300RAO	Reamer Attachment - Style AO			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-RB0275	ROUND BURR, STERILE 125 MM, DIA. 2.7 MM			IIa	45553	Shaver and Power Systems	6	II	1/21/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-RB040	Round Burr, 165 mm dia 4			IIa	45553	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-RB0705	ROUND BURR, STERILE 135 MM, DIA. 7 MM			IIa	45553	Shaver and Power Systems	6	II	1/21/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-300-RB070W	Round Burr w/flat tip 165 dia7			IIa	45553	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300RJ	Reamer Jacobs Chuck 0-4.0 mm			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300SAG	Saw Attachment - Sagittal			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300SR	Saw Attachment - Reciprocating			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-300WD16	Wire Driver Attachment 0.6-1.6 mm			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-3610NSD-2	Flexible 1.8 mm ShaverDrill™ for FiberTak® Soft Anchor with Flexible Obturator, Sharp			IIa	36224	Shaver and Power Systems	9	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-3657SD	2.6 mm ShaverDrill™ for FiberTak® Soft Anchor			IIa	36224	Shaver and Power Systems	9	II	5/25/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-400	DrillSaw Sports 400 System, Handpiece			IIa	66243	Shaver and Power Systems	9	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-400AEL	Adapter for radiolucet angular drive			IIa	66243	Shaver and Power Systems	6	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-400ATK	DrillSaw Sports 400 System, Aseptic Transfer Kit for AR-400			IIa	66243	Shaver and Power Systems	9	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-400ATK-1	DrillSaw Sports 400 System Aseptic Transfer Kit for AR-400			IIa	32033	Shaver and Power Systems	9	II	1/22/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-400B	DrillSaw Sports 400 System Attachment, Burr 1.35 mm			IIa	66243	Shaver and Power Systems	9	II	9/16/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-400DAO	DrillSaw Sports 400 System, Drill Attachment, Style AO			IIa	66243	Shaver and Power Systems	9	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-400DHA	Drill Attachment - Harris			IIa	66243	Shaver and Power Systems	6	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-400DHS	Attachment - Dynamic Hip Screw			IIa	66243	Shaver and Power Systems	6	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-400DI40	Drill Jacobs Chuck 0 - 4.0 mm			IIa	66243	Shaver and Power Systems	6	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-400DI74	DrillSaw Sports 400 System, Drill Jacobs Chuck, 0-7.4 mm			IIa	66243	Shaver and Power Systems	9	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-400DIH50	Drill Jacobs Chuck Hybrid 0-5.0 mm			IIa	66243	Shaver and Power Systems	6	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-400DIH74	Drill Jacobs Chuck Hybrid 0-7.4 mm			IIa	66243	Shaver and Power Systems	6	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-400DIK74	DrillSaw Sports 400 System, Drill Keyless Chuck, 0.6-7.4 mm			IIa	66243	Shaver and Power Systems	9	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-400DS	Drill Saw Sports 400 SystemDedicated Saw Handpiece			IIa	66243	Shaver and Power Systems	9	II	12/13/2023
Arthrex, Inc.	Naples, FL	CE 85507	AR-400PRMT	Power Reamer attachment (modified trinkle connector)			IIa	66243	Shaver and Power Systems	9	II	12/13/2023
Arthrex, Inc.	Naples, FL	CE 85507	AR-400PRHU	Power Reamer attachment (Hudson connector)			IIa	66243	Shaver and Power Systems	9	II	12/13/2023
Arthrex, Inc.	Naples, FL	CE 85507	AR-400PRAD	Power Reamer attachment (AO connector)			IIa	66243	Shaver and Power Systems	9	II	12/13/2023
Arthrex, Inc.	Naples, FL	CE 85507	AR-400SR	Reciprocating Saw attachment			IIa	66243	Shaver and Power Systems	9	II	12/13/2023
Arthrex, Inc.	Naples, FL	CE 85507	AR-400DT	Drill Attachment - Trinkle			IIa	66243	Shaver and Power Systems	6	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-400DZH	Drill Attachment-Style Zimmer / Hudson			IIa	66243	Shaver and Power Systems	6	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-400ILD	DrillSaw Sports 400 System Attachment, J-Latch, 2.35 mm Diameter, Round Shanks			IIa	66243	Shaver and Power Systems	9	II	8/2/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-400PD	PIN DRIVER ATTACHMENT, 0-3.2MM			IIa	66243	Shaver and Power Systems	6	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-400RAOP	Reamer Attachment - Style AO Protek			IIa	66243	Shaver and Power Systems	6	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-400RIHU	Reamer Attachment - Style Hudson			IIa	66243	Shaver and Power Systems	6	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-400RI74	Reamer Jacobs Chuck 0 - 7.4 mm			IIa	66243	Shaver and Power Systems	6	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-400RIH74	Reamer Jacobs Chuck Hybrid 0-7.4 mm			IIa	66243	Shaver and Power Systems	6	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-400RZH	Reamer Attachment-Style Zimmer / Hudson			IIa	66243	Shaver and Power Systems	6	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-400SAG	DrillSaw Sports 400 System, Saw Attachment, Sagittal			IIa	66243	Shaver and Power Systems	9	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-400UB	DrillSaw Sport 400™ System Battery Pack, Non-Sterile for AR-400			IIa	66243	Shaver and Power Systems	9	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-400UBC	DrillSaw Sports 400™ System, Universal Battery Charger for AR-400/AR-300 and AR-600 Batteries			IIa	66243	Shaver and Power Systems	9	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-400UBC-3	DrillSaw Sports 400™ System, Universal Battery Charger Charging Bays for AR-300/600 Batteries			IIa	66243	Shaver and Power Systems	9	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-400UBC-4	DrillSaw Sports 400™ System, Universal Battery Charger Charging Bays for AR-400 Batteries			IIa	66243	Shaver and Power Systems	9	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-400UBH	DrillSaw Sports 400 System, Li-Ion Battery Housing for AR-400			IIa	66243	Shaver and Power Systems	9	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-400UBH-1	DrillSaw Sports 400 System Li-Ion Battery Housing for AR-400			IIa	36534	Shaver and Power Systems	9	II	1/22/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-4150AOC	CANNULATED AO ADAPTER			IIa	43962	Shaver and Power Systems	6	II	12/6/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-600	Arthrex AR-600 Handpiece			IIa	66243	Shaver and Power Systems	6	II	4/25/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0008	Arthrex Power System 600, 90 x 13 x 1.0 mm Sagittal Saw Blade for Arthrex 600			IIa	43376	Shaver and Power Systems	6	II	7/24/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0015	Arthrex Power System 600, 90 x 13 x 1.27 mm Sagittal Saw Blade for Arthrex 600			IIa	43376	Shaver and Power Systems	6	II	7/24/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0025	Arthrex Power System 600, 90 (86) x 19 x 1.27 mm Sagittal Saw Blade for Arthrex 600			IIa	43376	Shaver and Power Systems	6	II	4/11/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0035	Arthrex Power System 600, 90 x 25.4 x 1.0 mm Sagittal Saw Blade for Arthrex 600			IIa	43376	Shaver and Power Systems	6	II	3/18/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0045	Arthrex Power System 600, 90 x 25.4 x 1.19 mm Sagittal Saw Blade for Arthrex 600			IIa	43376	Shaver and Power Systems	6	II	3/18/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0055	Arthrex Power System 600, 90 x 25.4 x 1.27 mm Sagittal Saw Blade for Arthrex 600			IIa	43376	Shaver and Power Systems	6	II	3/18/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0065	Arthrex Power System 600, 90 x 25.4 x 1.47 mm Sagittal Saw Blade for Arthrex 600			IIa	43376	Shaver and Power Systems	6	II	3/18/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0075	Arthrex Power System 600, 90 x 13 x 1.19 mm Sagittal Saw Blade for Arthrex 600			IIa	43376	Shaver and Power Systems	6	II	7/24/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0105	Arthrex Power System 600, 90 x 19 x 1.0 mm Sagittal Saw Blade for Arthrex 600			IIa	43376	Shaver and Power Systems	6	II	7/24/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0115	Arthrex Power System 600, 90 x 19 x 1.37 mm Sagittal Saw Blade for Arthrex 600			IIa	43376	Shaver and Power Systems	6	II	7/24/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0125	Arthrex Power System 600, 105 x 19 x 1.27 mm Sagittal Saw Blade for Arthrex 600			IIa	43376	Shaver and Power Systems	6	II	7/24/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0135	SAGITTAL SPEEDOUT BLADE for AR-600			IIa	43376	Shaver and Power Systems	6	II	3/21/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0208	600 RECIPROCATING SAW BLADE 88X13.4X1.1 mm			IIa	45493	Shaver and Power Systems	6	II	11/14/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0215	600 RECIPROCATING SAW BLADE 52.8X10X1.1 mm			IIa	45493	Shaver and Power Systems	6	II	11/14/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0225	SAW BLADE, 600, Reciprocating			IIa	45493	Shaver and Power Systems	6	II	10/24/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0255	Reciprocating Saw Blade for Arthrex, 600 32.8 x 9.5 x 1.1 mm			IIa	45493	Shaver and Power Systems	6	II	1/21/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0265	RECIPROCATING SAW BLADE F/AR-600 STERIL			IIa	43376	Shaver and Power Systems	6	II	8/2/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0505	SAGITTAL SAW BLADE 65X46X0.6MM STR			IIa	43376	Shaver and Power Systems	6	II	8/2/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0515	SAW BLADE, 600, SAGITTAL, 65 x 27 x 0.8 MM			IIa	43376	Shaver and Power Systems	6	II	10/24/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0525	SAW BLADE, 600, SAGITTAL, 65 x 18 x 0.8 MM			IIa	43376	Shaver and Power Systems	6	II	10/24/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0535	600 SAGITTAL SAW BLADE 45 x 9 x 0.6 mm			IIa	46476	Shaver and Power Systems	6	II	11/14/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-0605	Sagittal Saw Blade for Arthrex 600 27 x 65 x 1.2 mm			IIa	43376	Shaver and Power Systems	6	II	11/4/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-1005	600 SAGITTAL SAW BLADE 90 x 13 x .90 MM			IIa	43376	Shaver and Power Systems	6	II	3/5/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-1015	600 SAGITTAL SAW BLADE 90 X 13 X 1.27 MM			IIa	43376	Shaver and Power Systems	6	II	3/5/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-1035	600 SAGITTAL SAW BLADE 90 X 19 X 1.27 MM			IIa	43376	Shaver and Power Systems	6	II	3/5/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-1035	600 SAGITTAL SAW BLADE 90 X 25.4 X .90 MM			IIa	43376	Shaver and Power Systems	6	II	3/5/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-1045	600 SAGITTAL SAW BLADE 90 X 25.4 X 1.19 MM			IIa	43376	Shaver and Power Systems	6	II	3/5/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-1055	600 SAGITTAL SAW BLADE 90 X 25.4 X 1.27 MM			IIa	43376	Shaver and Power Systems	6	II	3/5/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-1065	600 SAGITTAL SAW BLADE 90 X 25.4 X 1.47 MM			IIa	43376	Shaver and Power Systems	6	II	3/5/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-1075	600 SAGITTAL SAW BLADE 45 X 8.5 X .38MM			IIa	43376	Shaver and Power Systems	6	II	3/5/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-1085	600 SAGITTAL SAW BLADE 130 X 19 X 1.27 MM			IIa	43376	Shaver and Power Systems	6	II	3/5/2009

Manufacturer name:	Manufacturing location:	EC QA Cert. number:	Product Code:	Product Name:	Portfolio / PROFIT CENTER	Include in MDR Submission? ("N/A- new MDR submission" means the device is a new addition and has no previous MDD certificate)	Class:	GMDN Code:	TF	Rule:	Annex:	First DoC
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-100S	600 SAG BLD, STRL, 17 X 8.5 X 6 WITH STOP			IIa	43376	Shaver and Power Systems	6	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-110S	600 SAGITTAL SAW BLADE 90 X 19 X 1.0 MM			IIa	43376	Shaver and Power Systems	6	II	12/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-111S	600 SAGITTAL SAW BLADE 90 X 19 X 1.37 MM			IIa	43376	Shaver and Power Systems	6	II	12/14/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-150S	SAW BLADE, 600, SAGITTAL, WIDE FLARE			IIa	43376	Shaver and Power Systems	6	II	2/9/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-151S	65MM X 27MM X .8MM OFFSET TEETH			IIa	43376	Shaver and Power Systems	6	II	2/9/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-200S	600 RECIPROCATING SAW BLADE 88 X 1.09 MM			IIa	45493	Shaver and Power Systems	6	II	3/5/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-201S	600 RECIPROCATING SAW BLADE 52.8 X 1.09 MM			IIa	45493	Shaver and Power Systems	6	II	3/5/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-202S	600 RECIPROCATING SAW BLADE 73.5 X 1.00 MM			IIa	45493	Shaver and Power Systems	6	II	3/5/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-250S	600 RECIP SAW BLADE, DBL ROW, 15 X1.2 X13 MM			IIa	45493	Shaver and Power Systems	6	II	1/28/2011
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-300S	600 SAGITTAL BLADE MIS 90 x 13 x 1.0 mm			IIa	43376	Shaver and Power Systems	6	II	11/14/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-301S	600 SAGITTAL BLADE MIS 90X13X1.27 mm			IIa	43376	Shaver and Power Systems	6	II	11/14/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-302S	600 SAGITTAL BLADE MIS 90I86IX19X1.27 mm			IIa	43376	Shaver and Power Systems	6	II	11/14/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-303S	600 SAGITTAL BLADE MIS 90X25.4X1.0 mm			IIa	43376	Shaver and Power Systems	6	II	11/14/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-304S	600 SAGITTAL BLADE MIS 90X25.4X1.19 mm			IIa	43376	Shaver and Power Systems	6	II	11/14/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-305S	600 SAGITTAL BLADE MIS 90X25.4X1.27 mm			IIa	43376	Shaver and Power Systems	6	II	11/14/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-306S	600 SAGITTAL BLADE MIS 90 X 25.4 X 1.4 mm			IIa	43376	Shaver and Power Systems	6	II	8/2/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-307S	600 SAGITTAL BLADE MIS 90X13X1.19 mm			IIa	43376	Shaver and Power Systems	6	II	11/14/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-310S	600 SAGITTAL BLADE MIS 90X19X1.0 mm			IIa	43376	Shaver and Power Systems	6	II	11/14/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-311S	600 SAGITTAL BLADE MIS 90X19X1.37 mm			IIa	43376	Shaver and Power Systems	6	II	11/14/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-312S	600 SAGITTAL BLADE MIS 105X19X1.27 mm			IIa	43376	Shaver and Power Systems	6	II	11/14/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-313S	SAGITTAL SPEEDCUT BLADE 7/16"-600 MIS STR			IIa	43376	Shaver and Power Systems	6	II	2/7/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-350S	Sagittal Saw Blade for Arthrex 600 MIS, 65 x 46 x 0.6 mm			IIa	43376	Shaver and Power Systems	6	II	4/6/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-351S	600 SAGITTAL BLADE MIS 65X27X0.8 mm			IIa	43376	Shaver and Power Systems	6	II	11/14/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-352S	600 SAGITTAL BLADE MIS 65X18X0.8 mm			IIa	43376	Shaver and Power Systems	6	II	11/14/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600-353S	600 SAGITTAL BLADE MIS 45X9X0.6 mm			IIa	43376	Shaver and Power Systems	6	II	11/14/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-600ARL	Adapter for radiolucent angular drive			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600ATK	Aseptic Transfer Kit for AR-600			IIa	66243	Shaver and Power Systems	6	II	4/25/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600DAO	Drill Attachment Style AO			IIa	66243	Shaver and Power Systems	6	II	4/25/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600DAOP	Drill Attachment - Style AO Protek			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600DAOT	Drill Attachment - Style AO / Trinkle			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600DHS	Reamer Attachment Style DHS			IIa	43962	Shaver and Power Systems	6	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-600DHU	Drill Attachment Style Hudson			IIa	43962	Shaver and Power Systems	6	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-600DJ	Drill Jacobs Chuck 0 - 6.5 mm			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600DJH	Drill Jacobs Chuck Hybrid 0.6-7.4 mm			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600DK	Drill Keyless Chuck 0.6-7.4 mm			IIa	66243	Shaver and Power Systems	9	II	8/31/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600DZH	Drill Attachment - Style Zimmer / Hudson			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600HKEY	Replacement Key for Hybrid Chuck for AR-600			IIa	44605	Shaver and Power Systems	6	II	12/6/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-600KEY	Replacement Key for Jacobs Chuck for AR-600			IIa	44605	Shaver and Power Systems	6	II	12/6/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-600L	Battery Pack, U-Ion for AR-600			IIa	66243	Shaver and Power Systems	6	II	4/25/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600LBH	Li-Ion Battery Housing for AR-600			IIa	66243	Shaver and Power Systems	6	II	4/25/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600PD-2	Pin Driver Attachment 1.6-4.0 mm			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600PD-3	Pin Driver Attachment 0.8-4.0 mm			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600RAOP	Reamer Attachment - Style AO Protek			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600RHU	Reamer Attachment Style Hudson			IIa	43962	Shaver and Power Systems	6	II	11/10/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-600RJ	Reamer Jacobs Chuck			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600RK	Reamer Keyless Chuck			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600RZH	Reamer Attachment - Style Zimmer / Hudson			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600SAG	Saw Attachment Sagittal			IIa	66243	Shaver and Power Systems	6	II	4/25/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600SAGAO	Saw Attachment - Sagittal Style AO			IIa	66243	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600SAGMIS	SAW ATTACHMENT-SAG MINIMAL INVASIVE CUTS			IIa	66243	Shaver and Power Systems	9	II	3/8/2018
Arthrex, Inc.	Naples, FL	CE 85507	AR-600SAGS	Saw Attachment Sagittal for AR-300 blades			IIa	66243	Shaver and Power Systems	9	II	8/31/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600SR	Saw Attachment Reciprocating			IIa	66243	Shaver and Power Systems	6	II	4/25/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-600SRS	ARTHREX POWER SYSTEM 600 STERNUM SAW ATTACHMENT			IIa	66243	Shaver and Power Systems	6	II	1/21/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-600WD-2	Wire Driver Attachment 0.6-1.6 mm			IIa	37842	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-601-13089-090S	Sagittal Saw Blade 90mm x 13mm x 0.89mm			IIa	43390	Shaver and Power Systems	6	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-601-13119-090S	Sagittal Saw Blade 90mm x 13mm x 1.19mm			IIa	43390	Shaver and Power Systems	6	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-601-13127-070S	Sagittal Saw Blade 70mm x 13mm x 1.27mm			IIa	43390	Shaver and Power Systems	6	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-601-13127-090S	Sagittal Saw Blade 90mm x 13mm x 1.27mm			IIa	43390	Shaver and Power Systems	6	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-601-13137-070S	Sagittal Saw Blade 70mm x 13mm x 1.37mm			IIa	43390	Shaver and Power Systems	6	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-601-13137-075S	Sagittal Saw Blade 75mm x 13mm x 1.37mm			IIa	43390	Shaver and Power Systems	6	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-601-19089-075S	Sagittal Saw Blade 75mm x 19mm x 0.89mm			IIa	43390	Shaver and Power Systems	6	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-601-19089-090S	Sagittal Saw Blade 90mm x 19mm x 0.89mm			IIa	43390	Shaver and Power Systems	6	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-601-19119-090S	Sagittal Saw Blade 90mm x 19mm x 1.19mm			IIa	43390	Shaver and Power Systems	6	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-601-19127-075S	Sagittal Saw Blade 75mm x 19mm x 1.27mm			IIa	43390	Shaver and Power Systems	6	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-601-19127-090S	Sagittal Saw Blade 90mm x 19mm x 1.27mm			IIa	43390	Shaver and Power Systems	6	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-601-25089-075S	Sagittal Saw Blade 75mm x 25mm x 0.89mm			IIa	43390	Shaver and Power Systems	6	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-601-25089-090S	Sagittal Saw Blade 90mm x 25mm x 0.89mm			IIa	43390	Shaver and Power Systems	6	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-601-25127-090S	Sagittal Saw Blade 90mm x 25mm x 1.27mm			IIa	43390	Shaver and Power Systems	6	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-601-25147-090S	Sagittal Saw Blade 90mm x 25mm x 1.47mm			IIa	43390	Shaver and Power Systems	6	II	7/24/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-6400RBS	ROUND BURR, HL, 8 FLUTE, 4.0MM X 19CM			IIa	45553	Shaver and Power Systems	6	II	7/14/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-6400RRBE	Round Burr, Retractable, HL, 4.0 mm x 18 cm			IIa	36224	Shaver and Power Systems	6	II	2/7/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-6400RRBE-1	Round Burr, Retractable, HL, 4.0 mm x 18 cm			IIa	36224	Shaver and Power Systems	6	II	2/7/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-6420BC	BONE CUTTER, HL, 4.2MM X 19CM			IIa	41499	Shaver and Power Systems	6	II	12/21/2006
Arthrex, Inc.	Naples, FL	CE 85507	AR-6420CBC	CURVED BONE CUTTER, 4.20MM X 18CM			IIa	41499	Shaver and Power Systems	6	II	12/21/2006
Arthrex, Inc.	Naples, FL	CE 85507	AR-6420CDS	DISSECTOR, CURVED, HL, 4.2MM X 19CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-6420CEX	EXCALIBUR, CURVED, HL			IIa	41499	Shaver and Power Systems	6	II	6/21/2012
Arthrex, Inc.	Naples, FL	CE 85507	AR-6420CST	SABRETOOTH, CURVED, HL, 4.2MM X 19CM			IIa	41499	Shaver and Power Systems	6	II	7/14/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-6420CTD	Torpedo™ Shaver, Curved, Hip Length 4.2 mm x19 cm			IIa	41499	Shaver and Power Systems	6	II	12/8/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-6420CTD-1	Torpedo™ Shaver, Curved, Hip Length 4.2 mm x19 cm			IIa	41499	Shaver and Power Systems	6	II	12/8/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-6420DS	DISSECTOR, HL, 4.2MM X 19CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-6420EX	EXCALIBUR, HL, 4.2MM X 19CM			IIa	41499	Shaver and Power Systems	6	II	10/6/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-6420ST	SABRETOOTH, HL, 4.2MM X 19CM			IIa	45553	Shaver and Power Systems	6	II	10/6/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-6420TD	Torpedo, 4.2mm x 19cm			IIa	45553	Shaver and Power Systems	6	II	10/14/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-6420XBC	Bone Cutter, Convex Curved, HL, 4.2mm			IIa	41499	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-6420XDS	Dissector Convex, CRV, HL 4.2 x 19			IIa	41499	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-6420XEX	Excalibur Convex CRV, HL, 4.2 x 19			IIa	41499	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-6420XSY	Sabretooth Convex CRV HL4.2x19			IIa	41499	Shaver and Power Systems	9	II	9/16/2016

Manufacturer name	Manufacturing location	EC QA Cert. number:	Product Code:	Product Name:	Portfolio / PROFIT CENTER	Include in MDR Submission? ("N/A- new MDR submission" means the device is a new addition and has no previous MDD certificate)	Class:	GMDN Code:	TF	Rule:	Annex:	First DoC
Arthrex, Inc.	Naples, FL	CE 85507	AR-6480-IC	CABLE, POWER, DUALWAVE-SHAVER, 4"			IIa	47487	Shaver and Power Systems	6	II	12/6/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-6480-IC8	CABLE, POWER, DUALWAVE-SHAVER, 8"			IIa	47487	Shaver and Power Systems	6	II	12/6/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-6500RBE	ROUND BURR, HL, 8 FLUTE 5.0MM X 19CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-6500RRBE	Round Burr, Retractable, HL, 5.0 mm x 18 cm			IIa	36224	Shaver and Power Systems	6	II	2/7/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-6500RRBE-1	Round Burr, Retractable, HL, 5.0 mm x 18 cm			IIa	36224	Shaver and Power Systems	6	II	2/7/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-6500VBE	Burr, Round, Concave, HL, 8 Flute			IIa	45553	Shaver and Power Systems	6	II	8/15/2012
Arthrex, Inc.	Naples, FL	CE 85507	AR-6500XBE	Burr, Round, Convex, HL, 8 Flute			IIa	45553	Shaver and Power Systems	6	II	8/15/2012
Arthrex, Inc.	Naples, FL	CE 85507	AR-6550RRBE	Round Burr, Retractable, HL, 5.5 mm x 18 cm			IIa	36224	Shaver and Power Systems	6	II	2/7/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-6550RRBE-1	Round Burr, Retractable, HL, 5.5 mm x 18 cm			IIa	36224	Shaver and Power Systems	6	II	2/7/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-7200SR	SABRE, SJ, 2.0MM X 7CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-7200SR-1	SABRE, SJ, 2.0MM X 7CM			IIa	36224	Shaver and Power Systems	6	II	9/15/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-7285PB	SJ ROUND BURR, 2.85 MM X 7 CM			IIa	36249	Shaver and Power Systems	6	II	7/26/2004
Arthrex, Inc.	Naples, FL	CE 85507	AR-7285POB	BURR, OVAL, SJ, DIA 2.85MM X 7 CM			IIa	36249	Shaver and Power Systems	6	II	5/28/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-7300DS	DISSECTOR, SJ, 3.0MM X 7CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-7300DS-1	DISSECTOR, SJ, 3.0MM X 7CM			IIa	36224	Shaver and Power Systems	6	II	9/15/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-7300OBT	BURR, OVAL, SJ, 10 FLUTE, 3.0MM X 7CM			IIa	45553	Shaver and Power Systems	6	II	10/6/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-7300OBT-1	BUR, OVAL, SJ, 10 FLUT 3.0MM X 7CM			IIa	36224	Shaver and Power Systems	6	II	9/15/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-7300RBE	ROUND BURR, SJ, 8 FLUTE, 3.0MM X 7CM			IIa	45553	Shaver and Power Systems	6	II	10/6/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-7300SR	SABRE, SJ, 3.0MM X 7CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-7300TD	Torpedo, 3.0 mm, 7 cm			IIa	41499	Shaver and Power Systems	6	II	4/25/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-7350TD	Torpedo™ Shaver, Small Joint 3.5mm x 7cm			IIa	41499	Shaver and Power Systems	6	II	12/8/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-7350TD-1	Torpedo™ Shaver, Small Joint 3.5mm x 7cm			IIa	41499	Shaver and Power Systems	6	II	12/8/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-7385POB	SJ OVAL BURR, 3.85 MM X 7CM			IIa	36249	Shaver and Power Systems	6	II	5/28/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-7400HSD	4MM HOODLESS SHEATH OVAL BUR, PRC			IIa	45553	Shaver and Power Systems	6	II	9/13/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-7400OBE	4MM OVAL PRC BUR 8 FLUTES			IIa	45553	Shaver and Power Systems	6	II	9/13/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-7400RBE	4MM, 8 FLUTES ROUND BUR, PRC			IIa	45553	Shaver and Power Systems	6	II	9/13/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-7400TD	Torpedo, 4.0mm x 7cm			IIa	45553	Shaver and Power Systems	6	II	10/14/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8150PP-30	POWERPICK, 30 DEG, 1.5MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8150PP-30-1	POWERPICK, 30 DEG			IIa	45553	Shaver and Power Systems	6	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8150PP-45	POWERPICK, 45 DEG, 1.5MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8150PP-45-1	POWERPICK, 45 DEG			IIa	45553	Shaver and Power Systems	6	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8150PP-45	POWERPICK, 45 DEG			IIa	45553	Shaver and Power Systems	6	II	9/10/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-8150PP-45-1	POWERPICK, 45 DEG			IIa	45553	Shaver and Power Systems	6	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8230G	ADAPTEUR POWER SYSTEM CONTROL CONSOLE			IIa	36224	Shaver and Power Systems	6	II	4/4/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-8300	APSI CONTROL CONSOLE			IIa	36224	Shaver and Power Systems	9	II	10/15/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-830S	SYNERGY RESECTION SHAVER CONSOLE			IIa	36224	Shaver and Power Systems	9	II	7/22/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8310	APSI FOOTSWITCH, STANDARD			IIa	36336	Shaver and Power Systems	9	II	10/15/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-8310GP	APSI FOOTSWITCH, GAS PEDAL			IIa	36336	Shaver and Power Systems	9	II	10/15/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-8310SP	Footswitch for APS II Shaver System and DualWave Pump, low profile			IIa	36336	Shaver and Power Systems	9	II	6/16/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-831S	APS II FOOTSWITCH, MULTIFUNCTION, WIRELESS			IIa	36336	Shaver and Power Systems	9	II	8/3/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-831SC	APS II FOOTSWITCH, MULTIFUNCTION, CORDED			IIa	36336	Shaver and Power Systems	9	II	8/3/2007
Arthrex, Inc.	Naples, FL	CE 85507	AR-831SW	Synergy Resection™ Wireless Footswitch Kit			IIa	36336	Shaver and Power Systems	9	II	9/27/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-831SW-1	Synergy Resection™ Wireless Footswitch			IIa	36336	Shaver and Power Systems	9	II	9/27/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-831SW-2	Synergy Resection™ Wireless Footswitch Receiver			IIa	36336	Shaver and Power Systems	9	II	9/27/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8320C	APSI REPLACEMENT CABLE			IIa	36224	Shaver and Power Systems	9	II	10/15/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-8320F	APSI SHAVER HANDPIECE, FOOTSWITCH CONTROL			IIa	36336	Shaver and Power Systems	9	II	10/15/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-8330F	APS II SHAVER HANDPIECE, FOOTSWITCH CONTROL			IIa	36336	Shaver and Power Systems	9	II	8/28/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8330H	SHAVER HP, APSII, HAND CONTROL			IIa	53617	Shaver and Power Systems	6	II	9/16/2009
Arthrex, Inc.	Naples, FL	CE 85507	AR-8330RH	SHAVER HP, APSII, HAND CONTROL, BACKHAND			IIa	53617	Shaver and Power Systems	6	II	7/2/2012
Arthrex, Inc.	Naples, FL	CE 85507	AR-8330SI	Synergy Resection HP, SJ			IIa	36224	Shaver and Power Systems	6	II	6/15/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-8330SIO	O-Ring, Removable Valve Synergy Resection HP, SJ (Replacement Part)			IIa	36224	Shaver and Power Systems	6	II	6/15/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-8330SV	Removable Valve Synergy Resection HP, SJ (Replacement Part)			IIa	36224	Shaver and Power Systems	6	II	6/15/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-8330V	REMOVABLE VALVE, AR-8330 SERIES SHAVER HANDPIECES			IIa	36224	Shaver and Power Systems	6	II	12/6/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8330VO	O-RING, REMOVABLE VALVE, AR-8330 SERIES SHAVER HP			IIa	36224	Shaver and Power Systems	6	II	12/6/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-8332H	Synergy HP, Synergy, Handcontrol			IIa	36224	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8332RH	Synergy HP, Synergy, Handcontrol, Backhand			IIa	36224	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8340F	APSI CANNULATED DRILL HANDPIECE FOOTSWITCH			IIa	36336	Shaver and Power Systems	9	II	10/15/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-8350CD5	Curved Dissector			IIa	45553	Shaver and Power Systems	6	II	5/21/2012
Arthrex, Inc.	Naples, FL	CE 85507	AR-8350DS	DISSECTOR, 3.5MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	11/10/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8350PR	Reciprocating Rasp 3.5mm			IIa	41499	Shaver and Power Systems	6	II	6/19/2012
Arthrex, Inc.	Naples, FL	CE 85507	AR-8350PR-1	POWERASP, 3.5MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	9/15/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-8350ST	SABRETOOTH, 3.5MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8380BC	BONE CUTTER, 3.8 MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	11/10/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8380BC	DOUBLECUT, 3.8MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	1/4/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8380DS	DISSECTOR, 3.8 MM X 13 CM			IIa	41499	Shaver and Power Systems	6	II	11/10/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8380EC	END CUTTER, 3.8 MM X 13 CM			IIa	41499	Shaver and Power Systems	6	II	11/10/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8380EX	EXCALIBUR, 3.8 MM X 13 CM			IIa	41499	Shaver and Power Systems	6	II	11/10/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8380SR	SABRE, 3.8 MM X 13 CM			IIa	41499	Shaver and Power Systems	6	II	11/10/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8380ST	SABRETOOTH, 3.8 MM X 13 CM			IIa	41499	Shaver and Power Systems	6	II	11/10/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8380SW	SLOTTED WHISKER, 3.8 MM X 13 CM			IIa	41499	Shaver and Power Systems	6	II	11/10/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8385BC	BONE CUTTER, 3.85 MM X 12.5 CM			IIa	36249	Shaver and Power Systems	6	II	5/28/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-8385EF	FULL RADIUS RESECTOR, AGGRESSIVE, 3.85MMX12.5CM			IIa	41499	Shaver and Power Systems	6	II	7/26/2004
Arthrex, Inc.	Naples, FL	CE 85507	AR-8385ES	SERRATED TOOTH RESECTOR, 3.85 MM X 12.5 CM			IIa	41499	Shaver and Power Systems	6	II	5/19/2005
Arthrex, Inc.	Naples, FL	CE 85507	AR-8385POB	OVAL BURR, 3.85 MM X 12.5 CM			IIa	36249	Shaver and Power Systems	6	II	5/28/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-8385RPB	ROUND BURR, LR, 3.85 MM X 12.5 CM			IIa	36249	Shaver and Power Systems	6	II	5/28/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-8385RPBU	ROUND BURR, LR, 3.85 MM X 12.5 CM, UNSTERILE			IIa	36249	Shaver and Power Systems	6	II	5/28/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-8385SW	SLOTTED WHISKER, 3.85 MM X 12.5 MM			IIa	41499	Shaver and Power Systems	6	II	1/1/2002
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400BC	BONE CUTTER, 4.0MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400BC-1	BONE CUTTER, 4.0MM X 13CM			IIa	36224	Shaver and Power Systems	6	II	9/15/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400CBC	Bone Cutter Curved 4.0x13			IIa	41499	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400CDC	DoubleCut Curved 4.0x13			IIa	41499	Shaver and Power Systems	9	II	9/16/2016
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400CDS	DISSECTOR, CURVED 4.0 MMX 13 CM			IIa	41499	Shaver and Power Systems	6	II	11/10/2008

Manufacturer name:	Manufacturing location:	EC QA Cert. number:	Product Code:	Product Name:	Portfolio / PROFIT CENTER	Include in MDR Submission? ("N/A- new MDR submission" means the device is a new addition and has no previous MDD certificate)	Class:	GMDN Code:	TF	Rule:	Annex:	First DoC
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400CX	EXCALIBUR, CURVED 4.0MM X 13 CM			IIa	41499	Shaver and Power Systems	6	II	1/4/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400CR	CLEARCUT ROUND BURR, 8 FLUTE, 4.0MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400CS	SABRE, CURVED 4.0 MM X 13 CM			IIa	41499	Shaver and Power Systems	6	II	11/10/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400CS	CLEARCUT SLAP BURR, 6 FLUTE, 4.0MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400CT	SABRETOOTH, CURVED 4.0 MM X 13 CM			IIa	41499	Shaver and Power Systems	6	II	11/10/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400CTD	Curved Torpedo, 4mm			IIa	45553	Shaver and Power Systems	6	II	5/15/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400CTS	BURR, TR, CLEARCUT, 6 FLUTE, 4.0MM			IIa	45553	Shaver and Power Systems	6	II	5/11/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400DC	DOUBLECUT, 4.0 MM X 13 CM			IIa	41499	Shaver and Power Systems	6	II	11/10/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400DS	DISSECTOR, 4.0MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400DS-1	DISSECTOR, 4.0MM X 13CM			IIa	36224	Shaver and Power Systems	6	II	6/4/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400EX	EXCALIBUR, 4.0MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400EX-1	EXCALIBUR, 4.0MM X 13CM			IIa	36224	Shaver and Power Systems	6	II	9/15/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400HSO	HOODLESS SHEATH, OVAL BURR, 4.0 MM			IIa	45553	Shaver and Power Systems	6	II	7/14/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400OE	OVAL BURR, 8 FLUTE, 4.0MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400OE-1	BURR, OVAL, 8 FLUTE 4.0MM X 13CM			IIa	36224	Shaver and Power Systems	6	II	6/4/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400PR	Reciprocating Rasp 4.0mm			IIa	41499	Shaver and Power Systems	6	II	6/19/2012
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400RBE	ROUND BURR, 8 FLUTE, 4.0MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400SR	SABRE, 4.0MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400ST	SABRETOOTH, 4.0MM X 12.5CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400TD	TORPEDO, 4.0 MM			IIa	45553	Shaver and Power Systems	6	II	3/4/2013
Arthrex, Inc.	Naples, FL	CE 85507	AR-8400TD-1	TORPEDO, 4.0MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8420BC	BONE CUTTER, 4.20 MM X 12.5 CM			IIa	41499	Shaver and Power Systems	6	II	5/19/2005
Arthrex, Inc.	Naples, FL	CE 85507	AR-8450CS	CLEARCUT SLAP BURR, 6 FLUTE, 4.5MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8450CTS	BURR, TR, CLEARCUT, 6 FLUTE, 4.5MM			IIa	45553	Shaver and Power Systems	6	II	5/11/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-8485PTB	TAPERED BURR, 4.85 MM X 12.5 CM			IIa	36249	Shaver and Power Systems	6	II	5/28/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-8485RFB	ROUND BURR, LR, 4.85 MM X 12.5 CM			IIa	36249	Shaver and Power Systems	6	II	5/28/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-8485RFBU	ROUND BURR, LR, 4.85 MM X 12.5 CM, UNSTERILE			IIa	36249	Shaver and Power Systems	6	II	5/28/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500BC	BONE CUTTER, 5.0MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500BC-1	BONE CUTTER, 5.0MM X 13CM			IIa	36224	Shaver and Power Systems	6	II	9/15/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500BL	BLURR 5.0MM			IIa	45553	Shaver and Power Systems	6	II	2/9/2010
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500COE	CLEARCUT OVAL BURR, 8 FLUTE, 5.0MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500COS	CLEARCUT OVAL BURR, 8 FLUTE, 5.0MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500COT	CLEARCUT OVAL BURR, 12 FLUTE, 5.0MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500CR	CLEARCUT ROUND BURR, 8 FLUTE, 5.0MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500DS	DISSECTOR, 5.0MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500DS-1	DISSECTOR, 5.0MM X 13CM			IIa	36224	Shaver and Power Systems	6	II	9/15/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500EC	END CUTTER, 5.0MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500EX	EXCALIBUR, 5.0MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500FOE	FLUSHCUT OVAL BURR, 8 FLUTE, 5.0MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500FOS	FLUSHCUT OVAL BURR, 6 FLUTE, 5.0MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500FOT	FLUSHCUT OVAL BURR, 12 FLUTE, 5.0MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500HSO	HOODLESS SHEATH, OVAL / TAPERED BURR, 5.0 MM			IIa	45553	Shaver and Power Systems	6	II	7/14/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500OE	OVAL BURR, 8 FLUTE, 5.0MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500OE-1	BURR, OVAL, 8 FLUTE 5.0MM X 13CM			IIa	36224	Shaver and Power Systems	6	II	9/15/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500RBE	ROUND BURR, 8 FLUTE, 5.0MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500RFOE	FlushCut Oval Burr, Retractable, 5.0 mm x 13 cm			IIa	36224	Shaver and Power Systems	6	II	2/7/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500RFOE-1	FlushCut Oval Burr, Retractable, 5.0 mm x 13 cm			IIa	36224	Shaver and Power Systems	6	II	2/7/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500SR	SABRE, 5.0MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500ST	SABRETOOTH, 5.0MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500SW	SLOTTED WHISKER, 5.0MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500TBT	TAPERED BURR, 12 FLUTE, 5.0MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	7/14/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500TD	Torpedo, 5.0mm x 13cm			IIa	45553	Shaver and Power Systems	6	II	1/16/2014
Arthrex, Inc.	Naples, FL	CE 85507	AR-8500TD-1	TORPEDO, 5.0MM X 13 CM			IIa	45553	Shaver and Power Systems	6	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550BC	BONE CUTTER, 5.5MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550COE	CLEARCUT OVAL BURR, 8 FLUTE, 5.5MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550COS	CLEARCUT OVAL BURR, 8 FLUTE, 5.5MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550COT	CLEARCUT OVAL BURR, 12 FLUTE, 5.5MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550CR	CLEARCUT ROUND BURR, 8 FLUTE, 5.5MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550DC	DOUBLECUT, 5.5MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550DS	DISSECTOR, 5.5MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550EX	EXCALIBUR, 5.5MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550FOE	FLUSHCUT OVAL BURR, 8 FLUTE, 5.5MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550FOS	FLUSHCUT OVAL BURR, 6 FLUTE, 5.5MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550FOT	FLUSHCUT OVAL BURR, 12 FLUTE, 5.5MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550HSO	HOODLESS SHEATH, OVAL / TAPERED BURR, 5.5 MM			IIa	45553	Shaver and Power Systems	6	II	7/14/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550OBT	OVAL BURR, 12 FLUTE, 5.5MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	7/14/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550PR	Reciprocating Rasp 5.5mm			IIa	41499	Shaver and Power Systems	6	II	6/19/2012
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550PR-1	POWERASP, 5.5MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	10/6/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550RBE	ROUND BURR, 8 FLUTE, 5.5MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550RFOE	FlushCut Oval Burr, Retractable, 5.5 mm x 13 cm			IIa	36224	Shaver and Power Systems	6	II	2/7/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550RFOE-1	FlushCut Oval Burr, Retractable, 5.5 mm x 13 cm			IIa	36224	Shaver and Power Systems	6	II	2/7/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550SR	SABRE, 5.5MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550ST	SABRETOOTH, 5.5MM X 13CM			IIa	41499	Shaver and Power Systems	6	II	4/1/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8550TBT	TAPERED BURR, 12 FLUTE, 5.5MM X 13CM			IIa	45553	Shaver and Power Systems	6	II	7/14/2008
Arthrex, Inc.	Naples, FL	CE 85507	AR-8585EF	FULL RADIUS RESECTOR AGGRESSIVE 5.85MMX12.5CM			IIa	41499	Shaver and Power Systems	6	II	7/26/2004
Arthrex, Inc.	Naples, FL	CE 85507	AR-8585FBS	5.85MM X 12.5CM FLUSH CUT BURR			IIa	45553	Shaver and Power Systems	6	II	10/21/2006
Arthrex, Inc.	Naples, FL	CE 85507	AR-8585RFB	ROUND BURR, LR, 5.85 MM X 12.5 CM			IIa	36249	Shaver and Power Systems	6	II	5/28/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-8585RFBU	ROUND BURR, LR, 5.85 MM X 12.5 CM, UNSTERILE			IIa	36249	Shaver and Power Systems	6	II	5/28/2003
Arthrex, Inc.	Naples, FL	CE 85507	AR-9100PP-00	PowerPick, SI, SMALL HUB, 0"			IIa	45553	Shaver and Power Systems	6	II	12/8/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-9100PP-00-1	PowerPick™, 0", 4 mm Drill Depth, Small Hub, 1.0 mm x 7 cm, 1 pk			IIa	45553	Shaver and Power Systems	6	II	7/23/2019
Arthrex, Inc.	Naples, FL	CE 85507	AR-9100PP-45	PowerPick Instrument, 45° 4mm Drill Depth Small Hub 1.0mm (Single Pack)			IIa	64337	Shaver and Power Systems	6	II	6/16/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-9100PP-45-1	PowerPick Instrument, 45° 4mm Drill Depth Small Hub 1.0mm (Multi Pack)			IIa	64337	Shaver and Power Systems	6	II	6/16/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-9200SR	Sabre, Small Hub 2.0mm x 7cm			IIa	45553	Shaver and Power Systems	6	II	6/15/2015

Manufacturer name:	Manufacturing location:	EC QA Cert. number:	Product Code:	Product Name:	Portfolio / PROFIT CENTER	Include in MDR Submission? ("N/A- new MDR submission" means the device is a new addition and has no previous MDD certificate)	Class:	GMDN Code:	TF	Rule:	Annex:	First DoC:
Arthrex, Inc.	Naples, FL	CE 85507	AR-9280NOT	Nano Oval Burr, 10 Flute, Small Hub (update to Nano Oval Burr, 10 Flute)			IIa	45553	Shaver and Power Systems	6	II	7/30/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9280NOT-1	Nano Oval Burr, 10 Flute, Small Hub (update to Nano Oval Burr, 10 Flute)			IIa	45553	Shaver and Power Systems	6	II	7/30/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9280NSR	Nano Sabre Small Hub			IIa	41499	Shaver and Power Systems	6	II	7/30/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9280NSR-1	Nano Sabre Small Hub			IIa	41499	Shaver and Power Systems	6	II	7/30/2021
Arthrex, Inc.	Naples, FL	CE 85507	AR-9300DS	Dissector, Small Hub 3.0mm x 7cm			IIa	45553	Shaver and Power Systems	6	II	6/15/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-9300OBT	Burr, Oval, 10 Flute, Small Hub 3.0mm x 7cm			IIa	45553	Shaver and Power Systems	6	II	6/15/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-9300RBT	Burr, Round, 10 Flute Small Hub 3.0mm x 7cm			IIa	45553	Shaver and Power Systems	6	II	6/15/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-9300SR	Sabre, 3.0mm x 7 cm			IIa	36249	Shaver and Power Systems	6	II	6/16/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-9350DS	Dissector, Small Hub 3.5mm x 7cm			IIa	45553	Shaver and Power Systems	6	II	6/15/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-9350OBT	Burr, Oval, 10 Flute Small Hub 3.5mm x 7cm			IIa	45553	Shaver and Power Systems	6	II	6/15/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-9350PR	PowerRasp Small Hub 3.5mm x 7cm (5 Pack)			IIa	45553	Shaver and Power Systems	6	II	6/16/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-9350PR-1	PowerRasp Small Hub 3.5mm x 7cm (Single Pack)			IIa	45553	Shaver and Power Systems	6	II	6/4/2020
Arthrex, Inc.	Naples, FL	CE 85507	AR-9350RBT	Burr, Round, 8 Flute Small Hub 3.5mm x 7cm			IIa	45553	Shaver and Power Systems	6	II	6/15/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-9350SR	Sabre, Small Hub 3.0mm x 7cm			IIa	45553	Shaver and Power Systems	6	II	6/15/2015
Arthrex, Inc.	Naples, FL	CE 85507	AR-9350TD	Torpedo™ Shaver, SJ Small Hub 3.5 mm x 7cm			IIa	41499	Shaver and Power Systems	6	II	12/8/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-9350TD-1	Torpedo™ Shaver, SJ Small Hub 3.5 mm x 7cm			IIa	41499	Shaver and Power Systems	6	II	12/8/2017
Arthrex, Inc.	Naples, FL	CE 85507	AR-D8400EX	Excalibur 4.0mm x 13 cm			IIa	41499	Shaver and Power Systems	6	II	9/27/2019






DoC Shaver and Power System rev 36

Final Audit Report

2024-06-06

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