



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 4, 2017

Renovo, Inc.
% Mr. Robert Packard
Medical Device Academy, Inc.
345 Lincoln Hill Rd.
Shrewsbury, Vermont 05738

Re: K172092

Trade/Device Name: Reprocessed Shavers/Burs
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: September 21, 2017
Received: September 21, 2017

Dear Mr. Packard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

**Jennifer R.
Stevenson -S3**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K172092

Device Name

Reprocessed Linvatec Shavers/Burs

Indications for Use (Describe)

The Reprocessed Linvatec shavers and burs are intended for use with the Linvatec Integrated Drive/Pump System to perform resection of soft tissue and bone. The fields of application include Otolaryngology, Neurological Surgical, Orthopedic, and Spinal surgical procedures.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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**Reprocessed Single-Use Linvatec Shavers & Burs Device Models Subject to Clearance
(120 Linvatec devices in total)**

OEM Model #	Description	Diameter	Picture	OEM
DPS-C002	Large Hub Shaver Blades, UltraGator	4.2mm		Conmed/Linvatec
DPS-C003	Large Hub Shaver Blades, UltraGator	5.5mm		Conmed/Linvatec
DPS-C010	Large Hub Shaver Blades, UltraFRR	4.2mm		Conmed/Linvatec
DPS-C011	Large Hub Shaver Blades, UltraFRR	5.5mm		Conmed/Linvatec
DPS-C005	Large Hub Shaver Blades, UltraTiger	4.2mm		Conmed/Linvatec
9399A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Great White Blade	3.5mm		Conmed/Linvatec
9299A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Great White Blade	4.2mm		Conmed/Linvatec
9297A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Great White Blade	4.8mm		Conmed/Linvatec
9599A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Great White Blade	5.5mm		Conmed/Linvatec
EL9299	Large Hub Shaver Blades, Large Hub, Merlin, Shaver, Great White Blade	4.2mm		Conmed/Linvatec
35ULT-ST-ZZ	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Ultracut	3.5mm		Conmed/Linvatec
C9405	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Ultracut	4.2mm		Conmed/Linvatec
C9415	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Ultracut	5.5mm		Conmed/Linvatec
EL9405	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Ultracut	4.2mm		Conmed/Linvatec
9298A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Mako Blade	4.2mm		Conmed/Linvatec
C9299A	Large Hub Shaver Blades, Pre-Bent 15°, Great White Blade	4.2mm		Conmed/Linvatec
C9248	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Full-Radius Resector	3.5mm		Conmed/Linvatec
9247A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Full-Radius Resector	4.2mm		Conmed/Linvatec
C9245	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Full-Radius Resector	4.8mm		Conmed/Linvatec
9246A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Full-Radius Resector	5.5mm		Conmed/Linvatec

42FRR-RA-ZZ	Large Hub Shaver Blades, Large Hub, ReAct, Shaver, Great White Blade	3.5mm		Conmed/Linvatec
42FRR-RA-ZZ	Large Hub Shaver Blades, Large Hub, ReAct, Shaver, Great White Blade	4.2mm		Conmed/Linvatec
C9943A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Full-Radius Resector	2.0mm		Conmed/Linvatec
C9944A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Full-Radius Resector Blade	2.0mm		Conmed/Linvatec
C9264	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Gator Blade	3.5mm		Conmed/Linvatec
9263A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Gator Blade	4.2mm		Conmed/Linvatec
C9262	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Gator Blade	4.8mm		Conmed/Linvatec
9260A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Gator Blade	5.5mm		Conmed/Linvatec
35GTR-RA-ZZ	Large Hub Shaver Blades, Large Hub, ReAct, Shaver, Gator	3.5mm		Conmed/Linvatec
42GTR-RA-ZZ	Large Hub Shaver Blades, Large Hub, ReAct, Shaver, Gator	4.2mm		Conmed/Linvatec
EL9263A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Gator	4.2mm		Conmed/Linvatec
EL9260A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Gator	5.5mm		Conmed/Linvatec
C9960A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Gator	2.0mm		Conmed/Linvatec
C9961A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Gator	2.9mm		Conmed/Linvatec
C9253	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Cuda	3.5mm		Conmed/Linvatec
C9254	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Cuda	4.2mm		Conmed/Linvatec
C9258	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Cuda	4.8mm		Conmed/Linvatec
C9255	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Cuda	5.5mm		Conmed/Linvatec
P9355	Large Hub Shaver Blades, Large Hub, Merlin, Shaver, Cuda	3.7mm		Conmed/Linvatec
35CUD-RA-ZZ	Large Hub Shaver Blades, Large Hub, ReAct®, Shaver, Cuda	3.5mm		Conmed/Linvatec
42CUD-RA-ZZ	Large Hub Shaver Blades, Large Hub, ReAct, Shaver, Cuda	4.2mm		Conmed/Linvatec
C9951A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Cuda	2.0mm		Conmed/Linvatec
C9952A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Cuda	2.9mm		Conmed/Linvatec
C9240	Large Hub Shaver Blades, Large Hub, Sterling®, Shaver, Tiger®	3.5mm		Conmed/Linvatec
C9242	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Tiger	4.2mm		Conmed/Linvatec
35TGR-RA-ZZ	Large Hub Shaver Blades, Large Hub, ReAct, Shaver, Tiger	3.5mm		Conmed/Linvatec

42TGR-RA-ZZ	Large Hub Shaver Blades, Large Hub, ReAct, Shaver, Tiger	4.2mm		Conmed/Linvatec
C9283	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, End Cutter	3.5mm		Conmed/Linvatec
C9284	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, End Cutter	4.2mm		Conmed/Linvatec
C9290	Large Hub Burs and Routers, Large Hub, Sterling®, Shaver, Dragon End Cutter	3.5mm		Conmed/Linvatec
C9291	Large Hub Burs and Routers, Large Hub, Sterling, Shaver, Dragon End Cutter	4.2mm		Conmed/Linvatec
C9292	Large Hub Burs and Routers, Large Hub, Sterling, Shaver, Dragon End Cutter	5.5mm		Conmed/Linvatec
C9760	Large Hub Burs and Routers, Large Hub, Sterling, Shaver, Meniscus Cutter	3.5mm		Conmed/Linvatec
9761A	Large Hub Burs and Routers, Large Hub, Sterling, Shaver, Meniscus Cutter	4.2mm		Conmed/Linvatec
C9762	Large Hub Burs and Routers, Large Hub, Sterling, Shaver, Meniscus Cutter	5.5mm		Conmed/Linvatec
C9274	Large Hub Burs and Routers, Large Hub, Sterling, Shaver, Slotted Whisker	4.2mm		Conmed/Linvatec
C9275	Large Hub Burs and Routers, Large Hub, Sterling, Shaver, Slotted Whisker	5.5mm		Conmed/Linvatec
H9110	Large Hub Burs and Routers, Large Hub, Sterling®, Bur, Spherical	3.5mm		Conmed/Linvatec
H9111	Large Hub Burs and Routers, Large Hub, Sterling, Bur, Spherical	4.5mm		Conmed/Linvatec
H9112	Large Hub Burs and Routers, Large Hub, Sterling, Bur, Spherical	5.5mm		Conmed/Linvatec
H9112RH	Large Hub Burs and Routers, Large Hub, Sterling, Bur, Spherical, 20° Reduced Hood	5.5mm		Conmed/Linvatec
EL9111RH	Large Hub Burs and Routers, Large Hub, Extended Length, Sterling, Bur, Spherical, 20° Reduced Hood	4.5mm		Conmed/Linvatec
55SPH-EL-RH	Large Hub Burs and Routers, Large Hub, Extended Length, Sterling, Bur, Spherical 20° Reduced Hood	5.5mm		Conmed/Linvatec
C9911A	Large Hub Burs and Routers, Large Hub, Small Joint, Sterling, Bur, Spherical	2.9mm		Conmed/Linvatec
H9121	Large Hub Burs and Routers, Large Hub, Sterling, Bur, Tapered	4.0mm		Conmed/Linvatec
H9121RH	Large Hub Burs and Routers, Large Hub, Sterling, Bur, Tapered, 20° Reduced Hood	4.0mm		Conmed/Linvatec

H9101	Large Hub Burs and Routers, Large Hub, Sterling, Bur, Oval	4.0mm		Conmed/Linvatec
40VAL-ST-FH	Large Hub Burs and Routers, Large Hub, Sterling, Bur, Oval, Fully Hooded	4.0mm		Conmed/Linvatec
H9101RH	Large Hub Burs and Routers, Large Hub, Sterling, Bur, Oval, 20° Reduced Hood	4.0mm		Conmed/Linvatec
H9101LH	Large Hub Burs and Routers, Large Hub, Sterling, Bur, Oval, Left Helix	4.0mm		Conmed/Linvatec
H9103RH	Large Hub Burs and Routers, Large Hub, Sterling, Bur, Oval, 20° Reduced Hood	5.0mm		Conmed/Linvatec
H9102	Large Hub Burs and Routers, Large Hub, Sterling, Bur, Oval	6.0mm		Conmed/Linvatec
H9201LH	Large Hub Burs and Routers, Large Hub, Sterling, Bur, Oval, Left Helix	6.0mm		Conmed/Linvatec
EL9101	Large Hub Burs and Routers, Large Hub, Extended Length, Sterling, Bur, Oval	4.0mm		Conmed/Linvatec
60VAL-EL-RH	Large Hub Burs and Routers, Large Hub, Sterling, Bur, Oval, 20° Reduced Hood	6.0mm		Conmed/Linvatec
H9118	Large Hub Burs and Routers, Large Hub, Sterling®, Bur, Cyclone	4.5mm		Conmed/Linvatec
H9119	Large Hub Burs and Routers, Large Hub, Sterling, Bur, Cyclone	5.5mm		Conmed/Linvatec
H9131	Large Hub Burs and Routers, Large Hub, Sterling, Router, Vortex, 5 Flutes, Hooded	4.5mm		Conmed/Linvatec
H9134	Large Hub Burs and Routers, Large Hub, Sterling, Router, Vortex, 5 Flutes, Unhooded	4.5mm		Conmed/Linvatec
H9132	Large Hub Burs and Routers, Large Hub, Sterling, Router, Vortex, 5 Flutes, Hooded	6.0mm		Conmed/Linvatec
29VTX-SJ-ZZ	Large Hub Burs and Routers, Large Hub, Small Joint, Sterling, Bur, Vortex Router	2.9mm		Conmed/Linvatec
35VTX-SJ-ZZ	Large Hub Burs and Routers, Large Hub, Small Joint, Sterling, Bur, Vortex Router	3.5mm		Conmed/Linvatec
H9133	Large Hub Burs and Routers, Large Hub, Sterling, Lighting	4.5mm		Conmed/Linvatec
M9299A	Micro Hub Blades, Micro Hub, Sterling®, Shaver, Great White	4.2mm		Conmed/Linvatec

M9298A	Micro Hub Blades, Micro Hub, Sterling, Shaver, Mako	4.2mm		Conmed/Linvatec
C9940	Micro Hub Blades, Micro Hub, Sterling®, Blade, Full-Radius Resector	2.0mm		Conmed/Linvatec
C9941	Micro Hub Blades, Micro Hub, Sterling, Blade, Full-Radius Resector	2.9mm		Conmed/Linvatec
C9942	Micro Hub Blades, Micro Hub, Sterling, Blade, Full-Radius Resector	3.5mm		Conmed/Linvatec
MC9248	Micro Hub Blades, Micro Hub, Sterling, Blade, Full-Radius Resector	3.5mm		Conmed/Linvatec
M9247A	Micro Hub Blades, Micro Hub, Sterling, Blade, Full-Radius Resector	4.2mm		Conmed/Linvatec
C9960	Micro Hub Blades, Micro Hub, Sterling, Blade, Gator	2.0mm		Conmed/Linvatec
C9961	Micro Hub Blades, Micro Hub, Sterling, Blade, Gator	2.9mm		Conmed/Linvatec
C9962	Micro Hub Blades, Micro Hub, Sterling, Blade, Gator	3.5mm		Conmed/Linvatec
MC9264	Micro Hub Blades, Micro Hub, Sterling, Blade, Gator	3.5mm		Conmed/Linvatec
MC9263A	Micro Hub Blades, Micro Hub, Sterling, Blade, Gator	4.2mm		Conmed/Linvatec
C9950	Micro Hub Blades, Micro Hub, Sterling®, Blade, Cuda	2.0mm		Conmed/Linvatec
C9951	Micro Hub Blades, Micro Hub, Sterling, Blade, Cuda	2.9mm		Conmed/Linvatec
C9952	Micro Hub Blades, Micro Hub, Sterling, Blade, Cuda	3.5mm		Conmed/Linvatec
MC9253	Micro Hub Blades, Micro Hub, Sterling, Blade, Cuda	3.5mm		Conmed/Linvatec
MC9254	Micro Hub Blades, Micro Hub, Sterling, Blade, Cuda	4.2mm		Conmed/Linvatec
MC9258	Micro Hub Blades, Micro Hub, Sterling, Blade, Cuda	4.8mm		Conmed/Linvatec
MC9290	Micro Hub Blade, Micro Hub, Sterling, Blade, Dragon, End Cutters	3.5mm		Conmed/Linvatec
MC9291	Micro Hub Blades, Micro Hub, Sterling, Blade, Dragon, End Cutter	4.2mm		Conmed/Linvatec
MC9292	Micro Hub Blades, Micro Hub, Sterling, Blade, Dragon, End Cutter	5.5mm		Conmed/Linvatec
C9981	Micro Hub Blades, Micro Hub, Sterling, Blade, Slotted Whisker	2.9mm		Conmed/Linvatec
MC9274	Micro Hub Blades, Micro Hub, Sterling, Blade, Slotted Whisker	4.2mm		Conmed/Linvatec

C9911A	Large Hub Burs and Routers, Large Hub, Sterling, Bur, Spherical	2.9mm		Conmed/Linvatec
C9912	Micro Hub Burs and Routers, Micro Hub, Sterling, Bur, Spherical	3.5mm		Conmed/Linvatec
MH9111	Micro Hub Burs and Routers, Micro Hub, Sterling, Bur, Spherical	4.5mm		Conmed/Linvatec
MH9112	Micro Hub Burs and Routers, Micro Hub, Sterling, Bur, Spherical	5.5mm		Conmed/Linvatec
MH9102	Micro Hub Burs and Routers, Micro Hub, Sterling, Bur, Oval	6.0mm		Conmed/Linvatec
MC9106	Micro Hub Burs and Routers, Micro Hub, Sterling, Bur, Oval, Left Helix	6.0mm		Conmed/Linvatec
C9990	Micro Hub Burs and Routers, Micro Hub, Sterling, Router, Vortex Two Flutes	2.9mm		Conmed/Linvatec
C9991	Micro Hub Burs and Routers, Micro Hub, Sterling, Router, Vortex Two Flutes	3.5mm		Conmed/Linvatec
MH9131	Micro Hub Burs and Routers, Micro Hub, Sterling, Router, Vortex Two Flutes	4.5mm		Conmed/Linvatec
MH9132	Micro Hub Burs and Routers, Micro Hub, Sterling, Router, Vortex Two Flutes	6.0mm		Conmed/Linvatec
C9405A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Ultracut	4.2mm		Conmed/Linvatec
C9298A	Large Hub Shaver Blades, Large Hub, Sterling, Shaver, Mako	5.5mm		Conmed/Linvatec
37GRW-ME-ZZ	Large Hub Shaver Blades, Large Hub, Merlin, Shaver, Great White	3.7mm		Conmed/Linvatec
C9299P	Large Hub Shaver Blades, Large Hub, Merlin, Shaver, Great White, Pre-Bent 15°	4.2mm		Conmed/Linvatec

Indications for Use

510(k) Number (if known)

K172092

Device Name

Reprocessed Smith & Nephew Shavers/Burs

Indications for Use (Describe)

The Reprocessed Smith & Nephew shavers and burs are intended for use with the Smith & Nephew DYONICS Power II Shaver System control unit, for resection of soft and osseous tissues including but not limited to, use in large articular cavities, small articular cavities, and Functional Endoscopic Sinus Surgery (FESS). The FESS application is limited to those small blades which are appropriate for the procedure.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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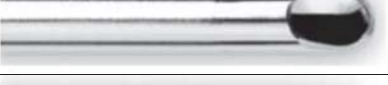
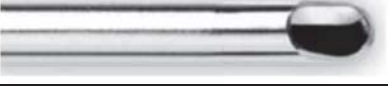
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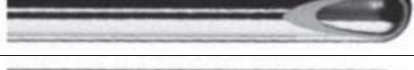
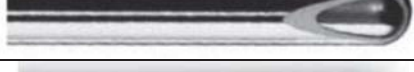
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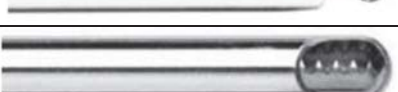
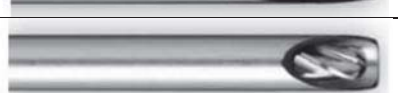
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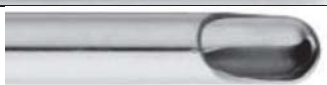
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**Reprocessed Single-Use Smith & Nephew Shavers & Burs Device Models Subject to Clearance
(63 Smith & Nephew devices in total)**

OEM Model #	Description	Diameter	Picture	OEM
7205316	DYONICS Straight Blades, TURBOWHISKER, Navy Blue Latch	4.5mm		Smith & Nephew
7205315	DYONICS Straight Blades TURBOTRIMMER, Powder Blue Latch	4.5mm		Smith & Nephew
7205310	DYONICS Straight Blades SYNOVATOR, Forest Green Latch	4.5mm		Smith & Nephew
7205311	DYONICS Straight Blades SYNOVATOR, Melon Yellow Latch	5.5mm		Smith & Nephew
7205308	DYONICS Straight Blades Cutter, Red Latch	3.5mm		Smith & Nephew
7205309	DYONICS Straight Blades Cutter, Blue Latch	4.5mm		Smith & Nephew
7205305	DYONICS Straight Blades Full Radius, Beige Latch	3.5mm		Smith & Nephew
7205306	DYONICS Straight Blades Full Radius, Yellow Latch	4.5mm		Smith & Nephew
7205341	DYONICS POWER Shaver Blades, 18cm working length Long Full Radius	4.5mm		Smith & Nephew
7205307	DYONICS Straight Blades Full Radius, Orange Latch	5.5mm		Smith & Nephew
7210751	DYONICS Straight Blades Full Radius ELITE, Beige Latch	3.5mm		Smith & Nephew
7210499	DYONICS Straight Blades Full Radius ELITE, Maroon Latch	4.5mm		Smith & Nephew
7205317	DYONICS Straight Blades RAZORCUT, Purple Latch	3.5mm		Smith & Nephew
7205318	DYONICS Straight Blades RAZORCUT, Pink Latch	4.5mm		Smith & Nephew
7205319	DYONICS Straight Blades RAZORCUT, Light Pink	5.5mm		Smith & Nephew
7205312	DYONICS Straight Blades INCISOR, Medium Grey Latch	3.5mm		Smith & Nephew

7205313	DYONICS Straight Blades INCISOR, Lime Green Latch	4.5mm		Smith & Nephew
7205343	DYONICS POWER Shaver Blades, 18cm working length Long INCISOR	4.5mm		Smith & Nephew
7205314	DYONICS Straight Blades INCISOR, Mocha Latch	5.5mm		Smith & Nephew
7205345	DYONICS Straight Blades INCISOR Plus, Violet Latch	4.5mm		Smith & Nephew
7205459	DYONICS Straight Blades INCISOR Plus, Teal Latch	5.5mm		Smith & Nephew
7209303	DYONICS Straight Blades Ultra Series TURBOWHISKER, Navy Blue Latch	4.5mm		Smith & Nephew
7210976	DYONICS Straight Blades INCISOR Plus ELITE, Slate Latch	4.5mm		Smith & Nephew
72200081	DYONICS Straight Blades INCISOR Plus ELITE, Lilac Latch	5.5mm		Smith & Nephew
72200414	DYONICS POWER Shaver Blades, 18cm working length Long INCISOR Plus ELITE	4.5mm		Smith & Nephew
72200095	DYONICS Straight Blades INCISOR Plus ELITE, White Latch	3.5mm		Smith & Nephew
72104486	DYONICS BONECUTTER Blades Full Radius BONECUTTER, Beige Latch	3.5mm		Smith & Nephew
7206011	DYONICS BONECUTTER Blades Full Radius BONECUTTER, Yellow Latch	4.5mm		Smith & Nephew
7206010	DYONICS BONECUTTER Blades Full Radius BONECUTTER, Orange Latch	5.5mm		Smith & Nephew
7206013	DYONICS BONECUTTER Blades SYNOVATOR w/Full Radius inner BONECUTTER, Forest Green Latch	4.5mm		Smith & Nephew
7206012	DYONICS BONECUTTER Blades SYNOVATOR w/Full Radius inner BONECUTTER, Melon Yellow Latch	5.5mm		Smith & Nephew
7205324	DYONICS Straight Burs Abrader, Aqua Latch	4.0mm		Smith & Nephew
7205325	DYONICS Straight Burs Abrader, Black Latch	5.5mm		Smith & Nephew
7209335	DYONICS Straight Burs Shielded, White Latch	4.5mm		Smith & Nephew

7205326	DYONICS Straight Burs Acromionizer, Mauve Latch	4.0mm		Smith & Nephew
7205327	DYONICS Straight Burs Acromionizer, Brown Latch	5.5mm		Smith & Nephew
7205727	DYONICS Straight Burs HELICUT, Slate Latch	4.5mm		Smith & Nephew
7205328	DYONICS Straight Burs NOTCHBLASTER, Lilac Latch	4.0mm		Smith & Nephew
7205329	DYONICS Straight Burs NOTCHBLASTER, Peach Latch	5.5mm		Smith & Nephew
7205668	DYONICS Straight Burs ACROMIOBLASTER, Sage Green Latch	4.0mm		Smith & Nephew
7205669	DYONICS Straight Burs ACROMIOBLASTER, Brick Red Latch	5.5mm		Smith & Nephew
7205330	DYONICS Straight Burs STONECUTTER, Maroon Latch	4.0mm		Smith & Nephew
72200082	DYONICS POWER Shaver Burrs, 18cm working length, partial hood Long Abrader	5.5mm		Smith & Nephew
72200729	DYONICS Straight Burs ELITE STONECUTTER, Maroon Latch	5.5mm		Smith & Nephew
72200730	DYONICS Straight Burs ELITE ACROMIOBLASTER, Sage Green Latch	4.0mm		Smith & Nephew
72200724	DYONICS Straight Burs ELITE Acromionizer, Mauve Latch	5.5mm		Smith & Nephew
72203127	DYONICS HIGH VISIBILITY Hip Burrs HIGH VISIBILITY Sheath Abrader Burr	5.5mm		Smith & Nephew
72203521	DYONICS Full Radius PLATINUM Blades Full Radius PLATINUM Blade	4.5mm		Smith & Nephew
72200723	DYONICS Straight Burs ELITE Abrader, Black Latch	5.5mm		Smith & Nephew
72200728	DYONICS Straight Burs ELITE STONECUTTER, Maroon Latch	4.0mm		Smith & Nephew
72203128	HIGH VISIBILITY Sheath Abrader Burr	4.0mm		Smith & Nephew
72202530	HIGH VISIBILITY Sheath Flat Top Burr	4.0mm		Smith & Nephew

7205320	ORBIT INCISOR™	4.5mm		Smith & Nephew
72200731	ELITE ACROMIOBLASTER	5.5mm		Smith & Nephew
72200727	ELITE NOTCHBLASTER	5.5mm		Smith & Nephew
72200726	ELITE NOTCHBLASTER	4.0mm		Smith & Nephew
7205331	ELITE ACROMIOBLASTER	5.5mm		Smith & Nephew
72202531	BONECUTTER PLATINUM Blade	4.5mm		Smith & Nephew
72203013	DYONICS INCISOR Plus PLATINUM	4.5mm		Smith & Nephew
72200725	ELITE Acromionizer	5.5mm		Smith & Nephew
7210486	Full Radius BONECUTTER	3.5mm		Smith & Nephew
72200722	ELITE Abrader	4.0mm		Smith & Nephew
3419	Full Radius	2.9mm		Smith & Nephew

Indications for Use

510(k) Number (if known)

K172092

Device Name

Reprocessed Stryker Shavers/Burs

Indications for Use (Describe)

The Reprocessed Stryker Shavers and Burs are intended for use with the Stryker Total Performance System Shaver handpiece and the Stryker Total Performance System by surgeons in the following orthopedic joints:

- > Knee
- > Shoulder
- > Ankle
- > Elbow
- > Wrist
- > Hip
- > Temporomandibular

The Reprocessed Stryker Shavers and Burs will be used to resect tissue and bur bone.

Examples of uses of the product would include resection of torn knee cartilage, subacromial decompression and resection of synovial tissue in other joints.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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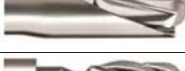
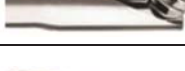
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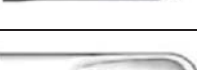
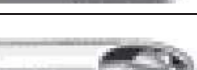
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**Reprocessed Single-Use Stryker Shavers & Burs Device Models Subject to Clearance
(72 Stryker devices in total)**

OEM Model #	Description	Diameter	Picture	OEM
375-535-000	Formula Series Cutters, Tomcat Cutters	3.5mm		Stryker
375-545-000	Formula Series Cutters, Tomcat Cutters	4.0mm		Stryker
375-555-000	Formula Series Cutters, Tomcat Cutters	5.0mm		Stryker
375-565-000	Formula Series Cutters, Tomcat Cutters	5.5mm		Stryker
375-542-000	Formula Series Cutters, Resector Cutters	4.0mm		Stryker
375-552-000	Formula Series Cutters, Resector Cutters	5.0mm		Stryker
375-562-000	Formula Series Cutters, Resector Cutters	5.5mm		Stryker
375-534-000	Formula Series Cutters, Aggressive Plus Cutters	3.5mm		Stryker
375-544-000	Formula Series Cutters, Aggressive Plus Cutters	4.0mm		Stryker
375-554-000	Formula Series Cutters, Aggressive Plus Cutters	5.0mm		Stryker
375-564-000	Formula Series Cutters, Aggressive Plus Cutters	5.5mm		Stryker
375-546-000	Formula Series Cutters, Scalloped Cutter	4.0mm		Stryker
375-566-000	Formula Series Cutters, Scalloped Cutter	5.5mm		Stryker
375-531-000	Formula Series Cutters, Cougar End Cutter	3.5mm		Stryker
375-541-000	Formula Series Cutters, Cougar End Cutter	4.0mm		Stryker
375-551-000	Formula Series Cutters, Cougar End Cutter	5.0mm		Stryker
375-737-000	Formula Series Cutters, End Cutter	3.5mm		Stryker
375-747-000	Formula Series Cutters, End Cutter	4.0mm		Stryker
375-757-000	Formula Series Cutters, End Cutter	5.0mm		Stryker
375-884-000	Formula Series Cutters, True End Cutter	4.0mm		Stryker
375-543-000	Formula Series Cutters, Double Bite Cutter	4.0mm		Stryker
375-548-000	Formula Series Cutters, Slotted Whisker Cutter	4.0mm		Stryker
375-558-000	Formula Series Cutters, Slotted Whisker Cutter	5.0mm		Stryker
375-549-000	Formula Series Cutters, Whisker Cutter	4.0mm		Stryker
375-941-012	Standard 12 Flute Barrel Bur	4.0mm		Stryker
375-951-012	Standard 12 Flute Barrel Bur	5.5mm		Stryker
375-941-000	Aggressive 6 Flute Barrel Bur	4.0mm		Stryker
375-951-100	Aggressive 6 Flute Barrel Bur	5.0mm		Stryker
375-951-000	Aggressive 6 Flute Barrel Bur	5.5mm		Stryker
375-941-200	Unhooded 6 Flute Barrel Bur	4.0mm		Stryker
375-951-200	Unhooded 6 Flute Barrel Bur	5.5mm		Stryker
375-940-012	Standard 12 Flute Round Bur	4.0mm		Stryker
375-950-112	Standard 12 Flute Round Bur	5.0mm		Stryker
375-950-012	Standard 12 Flute Round Bur	5.5mm		Stryker
375-930-000	Aggressive 6 Flute Round Bur	3.5mm		Stryker
375-940-000	Aggressive 6 Flute Round Bur	4.0mm		Stryker
375-950-100	Aggressive 6 Flute Round Bur	5.0mm		Stryker
375-950-000	Aggressive 6 Flute Round Bur	5.5mm		Stryker
375-940-200	Unhooded 6 Flute Round Bur	4.0mm		Stryker
375-950-200	Unhooded 6 Flute Round Bur	5.5mm		Stryker
375-941-200	Unhooded 6 Flute Barrel Bur	4.0mm		Stryker
375-951-200	Unhooded 6 Flute Barrel Bur	5.5mm		Stryker

375-952-000	Egg Bur 6 Flute	5.5mm		Stryker
375-941-500	Formula Series Specialty Bur, 6 Flute SLAP Bur	4.0mm		Stryker
375-450-500	Formula Series Specialty Bur, Auger Bur	5.0mm		Stryker
375-832-000	Formula Series Specialty Bur, Subchondral Drill (1.5mm Drill Tip)	4.0mm		Stryker
375-953-000	Formula Series Specialty Burs, 6 Flute Left Helix Barrel Bur	5.5mm		Stryker
375-953-012	Formula Series Specialty Burs, 12 Flute Left Helix Barrel Bur	5.5mm		Stryker
375-627-000	Formula Series Cutters and Burs, Small-Joint, Full Radius Cutter	2.5mm		Stryker
375-637-000	Formula Series Cutters and Burs, Small-Joint, Full Radius Cutter	3.5mm		Stryker
375-628-000	Formula Series Cutters and Burs, Small-Joint, Aggressive Plus Cutter	2.5mm		Stryker
375-638-000	Formula Series Cutters and Burs, Small-Joint, Aggressive Plus Cutter	3.5mm		Stryker
375-636-000	Formula Series Cutters and Burs, Small-Joint, Tomcat Cutter	3.5mm		Stryker
375-641-000	Formula Series Cutters and Burs, Small-Joint Hooded Abrasion Bur	2.0mm		Stryker
375-647-000	Formula Series Cutters and Burs, Small-Joint Hooded Abrasion Bur	3.0mm		Stryker
385-544-000	Formula Series Hip Length Cutters & Burs, Aggressive Plus, Long Hip Blade	4.0mm		Stryker
385-554-000	Formula Series Hip Length Cutters & Burs, Straight Aggressive Plus, Long Hip Blade	5.0mm		Stryker
385-545-000	Formula Series Hip Length Cutters & Burs, Tomcat, Long Hip Blade	4.0mm		Stryker
385-552-000	Formula Series Hip Length Cutters & Burs, Straight Resector, Long Hip Blade	5.0mm		Stryker
385-943-000	Formula Series Hip Length Cutters & Burs, Long Hip 8 Flute Pear Bur	4.0mm		Stryker
385-953-008	Formula Series Hip Length Cutters & Burs, Long Hip 8 Flute Pear Bur	5.5mm		Stryker
385-951-008	Formula Series Hip Length Cutters & Burs, Long Hip 8 Flute Round Bur	5.5mm		Stryker

385-950-008	Formula Series Hip Length Cutters & Burs, Long Hip 8 Flute Barrel Bur	5.5mm		Stryker
275-628-000	Small Joint Cutters & Burs, Small Joint Aggressive Cutter	2.5mm		Stryker
275-627-000	Small Joint Cutters & Burs, Small Joint Full Radius Cutter	2.5mm		Stryker
275-637-000	Small Joint Cutters & Burs, Small Joint Full Radius Cutter	3.5mm		Stryker
275-638-000	Small Joint Cutters & Burs, Small Joint Aggressive Cutter	2.5mm		Stryker
275-641-000	Small Joint Cutters & Burs, Small Joint Hooded Abrasion Bur	2.0mm		Stryker
275-647-000	Small Joint Cutters & Burs, Small Joint Hooded Abrasion Bur	3.0mm		Stryker
275-831-000	Small Joint Cutters & Burs, Small Joint Round Bur	3.0mm		Stryker
375-951-112	Standard 12 Flute Barrel Bur	5.0mm		Stryker
375-532-000	Resector Cutter	3.5mm		Stryker

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

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Date Prepared: October 2, 2017

III. DEVICE

Name of Device: Reprocessed Shavers/Burs
Classification Name: Arthroscope
Regulation: 21 CFR §888.1100
Regulatory Class: Class II
Product Classification Code: HRX

IV. OEM/PREDICATE DEVICES

Predicate Manufacturer: Stryker Endoscopy
Predicate Trade Name: Total Performance System Shaver
Predicate 510(k): K973195

Predicate Manufacturer: Linvatec Corporation
Predicate Trade Name: Integrated Drive/Pump System
Predicate 510(k): K981636

Predicate Manufacturer: Smith & Nephew, Inc., Endoscopy Division
Predicate Trade Name: DYONICS Power II Shaver System
Predicate 510(k): K062849

V. DEVICE DESCRIPTION

The Reprocessed Shavers and Burs are intended to be used for arthroscopic and laparoscopic surgical techniques. Shavers have sharp rotating inner blades housed in an outer shaft designed to cut tissue. Burs have an abrasive wearing surface that rotate in an outer sheath to grind down bone. The housing has a window cut out on one side of the distal end, allowing the bur to cut one part of the intended anatomy, while the adjacent one is still protected by the housing on the opposite side of the abrader, bur or blade.

There are various configurations of diameter, length, and cutting or grinding surfaces. The materials of construction are generally: metal shafts, lubricants (between the inner and outer components to reduce friction and heat), and polymer hubs bonded to the shafts. The polymer hub connects to a user-supplied motorized hand piece, which drives the internal abrader, bur or blade inside the outer housing. The handpiece provides suction to remove tissue which has been cut during the surgical procedure.

There are 39 Stryker shavers and 33 Stryker burs included in this submission. The Stryker shavers and burs are used with the Total Performance System Shaver handpiece. This handpiece is made of a motor housing with a coupling mechanism to secure the shavers/burs to the handpiece. The Stryker shavers and burs are intended to be used to resect tissue and bur bone in orthopedic joints such as the knee, shoulder, ankle, elbow, wrist, hip, etc.

There are 31 Smith & Nephew shavers and 32 Smith & Nephew burs included in this submission. The Smith & Nephew shavers and burs are intended to be used with the Smith & Nephew DYONICS Power II Shaver System control unit. This system is compatible with DYONICS POWER handpieces. It can be used in large or small joint cavities or in sinus surgery.

There are 94 ConMed/Linvatec shavers and 26 ConMed/Linvatec burs included in this submission. The Linvatec shavers and burs are intended to be used with the Linvatec Integrated Drive/Pump system. The system has three different handpieces that can be used for otolaryngology, neurological surgical, orthopedic, and spinal procedures.

VI. INDICATIONS FOR USE

The Reprocessed Linvatec shavers and burs are intended for use with the Linvatec Integrated Drive/Pump System to perform resection of soft tissue and bone. The fields of application include Otolaryngology, Neurological Surgical, Orthopedic, and Spinal surgical procedures.

The Reprocessed Smith & Nephew shavers and burs are intended for use with the Smith & Nephew DYONICS Power II Shaver System control unit, for resection of soft and osseous tissues including but not limited to, use in large articular cavities, small articular cavities, and Functional Endoscopic Sinus Surgery (FESS). The FESS application is limited to those small blades which are appropriate for the procedure.

The Reprocessed Stryker Shavers and Burs are intended for use with the Stryker Total Performance System Shaver handpiece and the Stryker Total Performance System by surgeons in the following orthopedic joints:

- > Knee
- > Shoulder
- > Ankle
- > Elbow
- > Wrist
- > Hip
- > Temporomandibular

The Reprocessed Stryker Shavers and Burs will be used to resect tissue and bur bone.

Examples of uses of the product would include resection of torn knee cartilage, subacromial decompression and resection of synovial tissue in other joints.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE OEM PREDICATE DEVICE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

- Indications for Use – The predicates and subject devices have equivalent indications for use; all are indicated for the resection of soft tissue and bone.
- Materials – The predicate and subject device materials are equivalent. The lubricants are not identical, but are equivalent in functional and biocompatible performance. The predicate device and subject device materials are identical to their respective predicate (OEM) devices, with the exception of the lubricant.
- Design – The predicate and subject devices are identical in design.
- Energy Source – The subject devices are not in themselves powered, but are powered by a user-provided handpiece. For the subject devices, the handpiece is the same handpiece used by the predicate (OEM).
- Performance Testing – The subject devices are reprocessed versions of the predicate (OEM) devices. The OEM devices are performance-tested cleared medical devices; therefore the performance testing consisted of side-by-side testing of the reprocessed devices to an identical new OEM device. The subject device was tested for sharpness and bending after three reprocessing cycles, and performed equivalently to the OEM device.
- Cleaning Validation – While it is very important to test the performance of the reprocessed device to ensure it performs as new; an important part of the risk management of a reprocessed device is the need to ensure cleanliness. A cleaning validation was performed to ensure that the reprocessing steps thoroughly cleaned and sanitized the devices so that they were as clean as a new OEM device.

VIII. SAFETY AND PERFORMANCE DATA

The following safety and performance data is provided in support of the substantial equivalence determination.

Performance Testing

- Functional Testing
 - Performance testing comparison against new OEM device (sharpness and bending)
 - Drop Testing comparison against new OEM device
- Product Stability
 - Shelf Life Testing 1-Year Accelerated Aging

Biocompatibility Testing

- Cytotoxicity
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Sensitization

Cleaning Validation

- Residual Protein and Carbohydrates
- Visual Inspection
- Cleaning Performance Qualification

Sterilization and Packaging

- EtO Sterilization Validation
- EtO Residuals Testing
- Simulated Shipment Testing

Electrical Safety and EMC Testing

Electrical safety and EMC testing were not applicable.

Animal Testing

Animal performance testing was not required to demonstrate safety and effectiveness.

Clinical Testing

Clinical testing was not required to demonstrate the safety and effectiveness of the Reprocessed Shavers/Burs. Substantial equivalence is based upon benchtop performance testing.

IX. CONCLUSIONS

Side by side testing ensured that the shavers and burs performed equivalently to the same device new from the OEM. Cleaning validations ensured that the devices are reprocessed and cleaned to the condition of a new OEM device. Therefore, based on a comparison of technological characteristics, indications for use, and performance comparison data, it can be concluded that the proposed Reprocessed Shavers/Burs are substantially equivalent to the OEM predicate device.