DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 17, 2017

Stryker Instruments
Dr. Joanna McCarthy
Senior Regulatory Affairs Specialist
Stryker Corporation
4100 E. Milham Ave.
Kalamazoo, MI 49009

Re: K161514
Trade/Device Name: Precision Thin Reciprocating Blade, 0.010in
Regulation Number: 21 CFR 874.4140
Regulation Name: Ear, Nose, and Throat Bur
Regulatory Class: Class I
Product Code: EQJ
Dated: December 13, 2016
Received: December 15, 2016

Dear Dr. McCarthy:

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 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 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,

Eric A. Mann -S

for Malvina Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161514

Device Name
Precision Thin Reciprocating Blade, 0.010in

Indications for Use *(Describe)*
Stryker's Precision Thin Reciprocating Blade, 0.010 inch (REF 5100-437-010) is a sterile, single use cutting accessory intended to cut bone in the posterior canal wall during an Otology 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Number: K161514

Section 5.1 Submitter

510(k) Owner**:** Stryker Instruments,

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Contact Person**:** Joanna McCarthy PhD, Senior Regulatory Affairs Specialist

Date Prepared: 27th May 2016

Section 5.2 Device Information

Trade Name: Precision Thin Reciprocating Blade, 0.010in.
Device Common Name: ENT Bur
Classification Name: Bur, Ear, Nose and Throat

FDA Product Code	Device	Regulation Number	Class
EQJ	*Bur, Ear, Nose and Throat*	21 CFR 874.4140	I

Table 5-1. Classification Data for Precision Thin Reciprocating Blade, 0.010in.

Section 5.3 Comparison against Regulation

Stryker currently markets 31 similar devices within the micro reciprocating saw blade family which are independently listed under the FDA product code EQJ. In this premarket notification all 31 devices covered under the EQJ regulation are compared to the subject device Precision Thin Reciprocating Blade, 0.010in based on their technological characteristics and general ENT indications. It is only the addition of the specific indication for the subject device Precision Thin Reciprocating Blade, 0.010in. that is being compared to the following regulation;

Regulation Description: Ear, Nose and Throat Bur
Regulation Number: 21 CFR 874.4140

Section 5.4 Reference Device

The Anspach Effort, Inc.:

Device Name:	Micro Reciprocating Saw Blade (REF MR-0580)
Type:	Reference Device
510(K) Number:	K131053- "ANSPACH XMAX, EMAX2 and EMAX2 Plus System with Otologic Attachment System" cleared under FDA Product Codes ERL and EQJ.
Description:	The primary comparator device (ENT Regulation 21CFR 874.4140) has successfully addressed decision points 1 to 4 in the 510(k) Decision Making Flowchart as per FDA) Guidance for Industry and FDA Staff, The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], dated July 28, 2014. However, the technological characteristics (design and material) of the Precision Thin Reciprocating Blade, 0.010in is compared to Anspach Micro Reciprocating Saw Blade, which is cleared through the 510(k) – K131053.

Table 5-2. Classification Data for Reference Device.

Section 5.5 Device Description

Stryker's Precision Thin Reciprocating Blade, 0.010in is a sterile, single use cutting accessory which is operated by a surgical drill (handpiece). This handpiece moves the Precision Thin Reciprocating Blade, 0.010in. in a reciprocating manner so that the blade removes bone material on the back stroke of its cut. The Precision Thin Reciprocating Blade, 0.010in. has a thickness of 0.010 inches and therefore can be used in surgical procedures where a narrow kerf width is required when cutting bone.

Section 5.6 Indications for Use

Stryker's Precision Thin Reciprocating Blade, 0.010 inch (REF 5100-437-010) is a sterile, single use cutting accessory intended to cut bone in the posterior canal wall during an Otology procedure.

Section 5.7 Comparison of Technological Characteristics against Regulation 21 CFR 874.4140 (ENT Burs) and reference device.

Feature	Comparator ENT Bur (21 CFR 874.4140)	Subject Device: Precision Thin Reciprocating Blade, 0.010in.	Justification
Product Class	Class I	Class I	**Identical**
Regulation	21 CFR 874.4140 - Bur, ear, nose and throat	21 CFR 874.4140 - Bur, ear, nose and throat	**Identical**
FDA Product Code	EQJ – Bur Ear, Nose and Throat	EQJ – Bur Ear, Nose and Throat	**Identical**
Intended Function	Intended to **cut bone**.	Intended to **cut bone**.	**Identical**
Patient Population	General	General	**Identical**
Indications For Use	An ear, nose, and throat bur is a device consisting of an interchangeable drill bit that is intended for use in an ear, nose, and throat electric or pneumatic surgical drill (874.4250) for incising or **removing bone in the ear**, nose, or throat area. The bur consists of a carbide cutting tip on a metal shank or a coating of diamond on a metal shank. The device is used in mastoid surgery, frontal sinus surgery, and surgery of the facial nerves.	Stryker's Precision Thin Reciprocating Blade, 0.010 inch (REF 5100-437-010) is a sterile, single use cutting accessory intended to **cut bone in the posterior canal wall** during an Otology procedure.	**Similar**
Contraindications	None known	None known	**Identical**

Feature	Comparator ENT Bur (21 CFR 874.4140)	Subject Device: Precision Thin Reciprocating Blade, 0.010in.	Justification
Conditions for Use	Single Use	Single Use	**Identical**
Principle of operation /Mechanism of Action	Legally marketed micro reciprocating blades listed under FDA product code EQJ (ENT Bur) are used in conjunction with an electric reciprocating handpiece (CORE™ Reciprocating Saws), a CORE™ Console and a footswitch or handswitch. When the system is assembled, the surgeon controls the footswitch; this modifies the electrical signal to the motor, controlling the speed of the cutting accessory.	Stryker's Precision Thin Reciprocating Blade, 0.010in. is used in conjunction with an electric motor (CORE™ Reciprocating Saws), a CORE™ Console and a footswitch. When the system is assembled, the surgeon controls the footswitch or handswitch; this modifies the electrical signal to the motor, controlling the speed of the cutting accessory.	**Identical**
Motor power supply	Powered by Electrical energy.	Electrical energy.	**Identical**
For use with a surgical drill (handpiece) per 21 CFR 874.4140	Legally marketed micro reciprocating blades - listed under FDA product code EQJ (ENT Bur) are used with the CORE™ Reciprocating Saws.	Used with the CORE™ Reciprocating Saws as indicated on the product label.	**Identical**
Source of Activation	Footswitch and Handswitch.	Footswitch and Handswitch.	**Identical**

Feature	Subject Device: Precision Thin Reciprocating Blade, 0.010in.	Reference Device: Anspach Micro Reciprocating Saw Blade (MR-0580)	Justification
Cutting Accessory Locking Mechanism	Tip and Blade Plug locking mechanism.	Chuck is tightened around shank.	**Similar**
Shank of the Cutting Accessory	0.125 - 0.124 inches	0.124 inches	**Identical**
Cutting Accessory Geometry	Cut Edge: 0.766 in. (19.5mm) Blade Height: 0.137 in. Cut Thickness: 0.010 in.	Cut Edge: 21.35 mm (0.84 in) Cut Thickness: 0.25 mm (0.010 in)	**Similar**
Cutting Accessory Length of exposure	1.42 in.	1.37 in.	**Similar**
Patient Contacting Material	Blade Arbor – Stainless Steel Blade - Stainless Steel Vacuum Brazing Paste - NICROBRAZ 51 S ALLOY.	Blade Arbor - Stainless Steel. Blade – Stainless Steel. Vacuum Brazing Paste – Unknown.	**Similar**
Sterilization	Supplied sterile, gamma irradiated.	Supplied sterile, gamma irradiated.	**Identical**
Sterility Assurance Level (SAL)	SAL of 10^{-6}	Minimum SAL of 10^{-6}	**Identical**
Shelf-Life	5 Years	Unknown	**Similar**
Packaging Configuration	Individually packaged in foil pouch with Polybag.	Tyvek / Film pouch with the internal packaging being a PETG clamshell blister.	**Similar**

Table 5-3: Comparative Device Justification Table.

Section 5.8 Performance Data

The following verification tests were performed which demonstrates that the device meets the performance requirements under its indications for use conditions.

- Kerf Width Testing
- Life, Simulated Use Testing
- Temperature Testing

Simulated use of a canal wall reconstruction was completed with 3 ENT surgeons for the specific indication in fresh cadaveric Human temporal bone. To supplement this cadaveric study design validation was also completed for the specific indication using PHACON's Temporal Bone Model with 8 ENT surgeons. This model was selected as a suitable cut media for design validation following a technical evaluation along with expert medical opinion. Collectively, the results of these performance tests demonstrate the functionality, integrity, safety and effectiveness of Stryker's Precision Thin Reciprocating Blade, 0.010in. for its intended use and support a determination of substantial equivalence to the regulation 21 CFR 874.4140 (ENT bur).

5.8.1 Biocompatibility Testing

The subject device Precision Thin Reciprocating Blade, 0.010in. is classified as external communicating device: tissue/bone/dentin with limited patient contact (< 24 hours).

The Biocompatibility evaluation was conducted in accordance with;

- AAMI/ANSI/ISO ISO 10993-1:2009/(R)2013, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and Guidance for Industry and FDA Staff.
- Draft Guidance for Industry and FDA Staff, Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" (Date April 23, 2013).
- FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," (Dated May 1, 1995).

Results of testing validate that the subject device is non-sensitizing, non-irritating and non-toxic (cytotoxic and systemic).

5.8.2 Clinical Studies

No clinical studies were performed to support substantial equivalence.

Section 5.9 Conclusions

The subject device Precision Thin Reciprocating Blade, 0.010in. is substantially equivalent in intended use, operating principle, fundamental technology, overall design and materials to ENT Burs as described in 21 CFR 874.4140.

Risk analysis for the subject device due to the addition of the specific indication reveals no new issues regarding safety or effectiveness.