DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 26, 2014

Stryker Corporation
Mr. Vishal Kanani
Sr. Regulatory Affairs Representative
4100 E. Milham Avenue
Kalamazoo, MI 49001

Re: K141935
Trade/Device Name: Stryker S2 Drill
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, Nose, and Throat Electric or Pneumatic Surgical Drill
Regulatory Class: Class II
Product Code: ERL, HBE, DZJ
Dated: August 25, 2014
Received: August 27, 2014

Dear Mr. Kanani:

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" (21CFR 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 yours,

Eric A. Mann -S

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

Enclosure

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)*

K141935

Device Name
Styker S2 Drill

Indications for Use *(Describe)*

The Stryker S2 Drill is intended for use with the Stryker Consolidated Operating Room Equipment (CORE) System. When used with a variety of attachments and cutting accessories, the drill is intended for use in cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to dental, ENT (ear, nose, and throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) Owner:

Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, MI 49001
(p) 269-323-7700
(f) 269-389-5412

Contact Person:

Vishal Kanani
Sr. Regulatory Affairs Representative

Registration Number:

1811755

Date Summary Prepared:

July 07, 2014

Trade Name(s):

Stryker S2 Drill

Common Name:

Ear, nose, and throat electric or pneumatic surgical drill.

Classification Data:

	Product Code	Device	Regulation Number	Class	Review Panel
Primary Code	ERL	Drill, Surgical, ENT (Electric or Pneumatic) Including Handpiece	21 CFR 874.4250	II	Ear, Nose and Throat
Secondary Codes	HBE	Drills, burs, trephines, and accessories (simple, powered)	21 CFR 872.4120	II	Neurology
	DZJ	Driver, wire, and bone drill, manual	21 CFR 872.4120	II	Dental

Predicate Device:

510(k) number	Product code	Trade name	Manufacturer
K112593	ERL	Stryker® Consolidated Operating Room Equipment (CORE) System	Stryker Instruments

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Indications for Use:	The Stryker S2 Drill is intended for use with the Stryker Consolidated Operating Room Equipment (CORE) System. When used with a variety of attachments and cutting accessories, the drill is intended for use in cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to dental, ENT (ear, nose, and throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.
Device Description:	The Stryker S2 Drill is an electric powered (40V DC) motor. When connected to the CORE console, it directly rotates cutting accessories up to speeds of 75,000 RPM.
Performance Data (Non Clinical Tests):	Following verification tests were performed which demonstrate that the design outputs of the modified device meet the design input requirements: • Verification of the improved rotor driveshaft • Simulated use tests • Temperature testing of different torque-speed setting Results of these tests demonstrate that the functionality, integrity, and safety and effectiveness of the Stryker S2 Drill is sufficient for their intended use and support a determination of substantial equivalence.
Clinical Tests:	No clinical testing was deemed necessary for this 510(k).
Conclusion/ Substantial Equivalence (SE) Rationale:	The Stryker S2 Drill is substantially equivalent in intended use, technological characteristics, safety, and effectiveness to the previously cleared Stryker CORE Sumex Drill. The products have the same fundamental scientific technology, basic design, functional characteristics and applications. The modifications introduced raise no new issues of safety and effectiveness. Therefore, the Stryker S2 Drill is substantially equivalent to the existing predicate device.

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Summary of Substantial Equivalence Table		
Description	**Stryker CORE Sumex Drill (Predicate)**	**Stryker S2 Drill (Subject)**
Intended Use	The Stryker Consolidated Operating Room Equipment (CORE) System is intended for use in cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to, dental, ENT (ear, nose, and throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.	The S2 Drill is intended for use with the Stryker Consolidated Operating Room Equipment (CORE) System. When used with a variety of attachments and cutting accessories, the drill is intended for use in cutting, drilling, reaming, decorticating, shaping and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to ENT, neuro, spine and Endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.
Housing Material	Stainless Steel	Stainless Steel and Aluminum
Motor Diameter	20mm	17mm
Length of the drill	105mm	123.5mm
Weight of the drill	399g	313g
Power source	40V DC Electric Motor connected via cable to CORE console	40V DC Electric Motor connected via cable to CORE console
Speed	0-75,000 rpm	0-75,000 rpm
Attachment retention method by drill	Mechanical lock activated by rotation of attachment onto drill	Mechanical lock activated by rotation of attachment onto drill
Mode of activation	Footswitch and Handswitch	Footswitch