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

May 22, 2015

Stryker Instruments
Mr. Deval Patel
Senior Regulatory Affairs Specialist
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K150801
Trade/Device Name: Stryker® Maestro™ Air Motors
Regulation Number: 21 CFR 882.4370
Regulation Name: Pneumatic cranial drill motor
Regulatory Class: Class II
Product Code: HBB
Dated: April 29, 2015
Received: April 30, 2015

Dear Mr. Patel:

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,

Jennifer R. Stevenson -S

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

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)*

K150801

Device Name
Stryker Maestro Air Motors

Indications for Use *(Describe)*

The Stryker® Consolidated Operating Room Equipment (CORE™) Maestro Air Pneumatic System is a pneumatically operated surgical instrument system. The pneumatic motor provides power to operate removable rotating surgical cutting tools and their accessories intended for use in neurosurgery, including craniotomy and spinal surgery; as well as ear, nose and throat (ENT), orthopedic, and general surgical applications including maxillofacial, craniofacial and sternotomy surgeries.

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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4100 E. Milham Ave.
Kalamazoo, MI 49001
t: 269 323 7700 f: 269 389 5412
www.stryker.com

K150801

510(k) Summary

Applicant	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, MI 49001 US
Contact	Deval Patel Senior Regulatory Affairs Specialist Phone: (269) 389- 5671 E-mail: Deval.Patel@stryker.com
Registration Number	1811755
Date Summary Prepared	March 25, 2015
Trade Name	Stryker® Maestro Air™ Motors
Common Name	Pneumatic Cranial Drill Motor
Classification Data	21 CFR 882.4370, Pneumatic Cranial Drill Motor, Product Code HBB, Class II 510(k)
Predicate Device	Stryker Maestro Pneumatic System, K041754
Indication for Use	The Stryker® Consolidated Operating Room Equipment (CORE ™) Maestro Air Pneumatic System is a pneumatically operated surgical instrument system. The pneumatic motor provides power to operate removable rotating surgical cutting tools and their accessories intended for use in neurosurgery, including craniotomy and spinal surgery; as well as ear, nose and throat (ENT), orthopedic, and general surgical applications including maxillofacial, craniofacial and sternotomy surgeries.

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Device Description	The Stryker® Maestro Air™ Motor(s) is a pneumatic motor powered by a regulated gas source. When connected to a gas source via tubing, the pneumatic motor operates at a normal operating pressure up to 150-psi (per square inch). The motor speed is controlled by a handswitch or a footpedal that connects to the motor and to a regulated gas source.
Performance Data (Non-Clinical Tests)	The results of the performance testing demonstrate that the functionality, integrity and safety and effectiveness of the Stryker Maestro Air Motors are sufficient for their intended use and support a determination of substantial equivalence to the predicate device.
Summary of Performance Testing	The following verification tests were performed on the subject device to demonstrate that the design outputs of the modified device meet the design input requirements. • Reliability Testing- Motor body, Handswitch mounting, Router Retention, Pneumatic Hose assembly and automated washing • Packaging Testing • Cleaning Testing • Sterilization Testing Results of these tests demonstrate that the functionality, integrity, and safety and effectiveness of the Stryker Maestro Air Motors are sufficient for their intended use and support a determination of the substantial equivalence.
Clinical Test	No Clinical Test was deemed necessary for this 510(k).
Predicate Comparison	Please refer to Table 6-1: for the predicate comparison.

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www.stryker.com

Table 6-1: *Summary of Predicate Comparison*

DESCRIPTION	***STRYKER MAESTRO PNEUMATIC SYSTEM [PREDICATE] K041754***	**STRYKER® MAESTRO AIR™ MOTORS *[SUBJECT]***
Classification of Device	Class II	Class II
Regulation	21 CFR 882.4370; Pneumatic Cranial Drill Motor	21 CFR 882.4370; Pneumatic Cranial Drill Motor
Product Code	HBB	HBB
Power source	Dry, Filtered, Compressed air or nitrogen	Dry, Filtered, Compressed air or nitrogen
Patient Population	General	General
Contraindications	None known	None known
Motor Type	High Speed, High Torque, Pneumatic Vane	High Speed, High Torque, Pneumatic Vane
Mode of Action	Footpedal and Handswitch	Footpedal and Handswitch
Operating Speed	Up to 75,000 rotations per minute	Up to 75,000 rotations per minute
Stall Torque	5.6 in-oz. @ 150 psi (per square inch)	6.7 in-oz. @ 150 psi (per square inch)
Maximum Operating Pressure	120 psi (per square inch)	Up to 150 psi (per square inch)
Grip Design	Smooth	Knurled
Router Retention Mechanism	Friction	Spring Collar
Method of Sterilization	Moist Heat (Steam)	Moist Heat (Steam)
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}
Method of Packaging	Packaged in a polybag case configuration	Packaged in a sealed air Korrvu retention Insert configuration

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Table 6-1: *Summary of Predicate Comparison (Continued)*

DESCRIPTION	***STRYKER MAESTRO PNEUMATIC SYSTEM [PREDICATE] K041754***	**STRYKER® MAESTRO AIR™ MOTORS *[SUBJECT]***
Cleaning Method	Manual	Manual and Mechanical (automated)
Weight of the Motor and Hose	2.05 lb.	1.65 lb.
Housing Material	Stainless Steel	Stainless Steel and Aluminum
Pneumatic Hose Assembly	Exhaust Hose: Flurosilicone Inlet Hose: Nitrile rubber	Exhaust Hose: Flurosilicone with silicone jacket and Slick Sil coating Inlet Hose: Nitrile rubber and neoprene

Conclusion/Substantial Equivalence Rationale

The Stryker Maestro Air Motors is substantially equivalent in intended use, technological characteristics, safety and effectiveness to the previously cleared Stryker Maestro Pneumatic System. 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 Maestro Air Motors is substantially equivalent to the existing predicate device.