

SEP - 7 2004

K041754

510(k) Summary

Trade Name: Stryker Maestro Pneumatic System

Common Name: Surgical Drill motors with accessories

Classification: Pneumatic cranial drill motors for neurosurgery (HBB)
Surgical drill for Ear, Nose, & Throat (ERL)
Pneumatic cranial drill motor (HBB)
Surgical Ear, Nose, & Throatbur (EQL)
Powered simple cranial drill, burrs, and accessories (HBE)
Blades, saw, surgical cardiovascular (DWH)

Equivalent to: **Medtronic Legend®**, Motor Drill Pneumatic (K020069),

Device Description: The Stryker Maestro Pneumatic System is a pneumatic, high-speed instrument system consisting of a motor (handpiece), hoses, and a variety of attachments and cutting accessories.

Intended Use: The Stryker Maestro 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.

Technological Comparison: The Stryker Maestro Pneumatic System has the same intended use as the **Medtronic Legend®**. This device and the predicate device have the same technological characteristics, the same operating principles, use the same patient contacting materials, and have similar performance characteristics.

Conclusions: Based upon the comparison to the predicate devices, the Stryker Maestro Pneumatic System is substantially equivalent to legally marketed devices.

Submitted by: Nicole Petty
Stryker Instruments
4100 E. Milham Ave.
Kalamazoo, MI 49001

269-323-7700

Summary Prepared: August 17, 2004



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Nicole Petty
Associate Manager, Regulatory Affairs
Stryker Corporation
Instrument Division
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

Re: K041754
Trade/Device Name: Stryker Maestro Pneumatic System
Regulation Number: 21 CFR 882.4370
Regulation Name: Pneumatic cranial drill motor
Regulatory Class: II
Product Code: HBB
Dated: August 17, 2004
Received: August 19, 2004

Dear Ms. Petty:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K041754
Device Name Stryker Maestro Pneumatic System

Indications

The Stryker Maestro 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.

Prescription Use X AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K041754