K090112

MAR 2 6 2009

5. 510(k) Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Establishment Registration Number: 1625507

Address of Manufacturer:
Medtronic Powered Surgical Solutions
4620 North Beach Street
Fort Worth, TX 76137
(817) 788-6400 Phone
(817) 788-6222 Facsimile

Contact Person: Jeffrey Henderson

Date: December 19, 2008

Trade or Proprietary Name: Midas Rex MR7 Pneumatic High Speed System

Common usual or Classification Name: Pneumatic Cranial Drill Motor, 21CFR882.4370 (HBB)
Instrument, surgical, orthopedic, pneumatic powered & Accessory/Attachment, 21CFR878.4820 (HSZ)

Description: The Midas Rex MR7 Pneumatic High Speed System includes a pneumatic motor; either the MR7 option which is foot controlled or the MR7t option which is finger controlled. A coaxial hose system, designed with an inner high-pressure supply hose located within an exhaust hose, connects the motor to the foot controller. One end of the coaxial hose system is permanently attached to the motor. The inner high-pressure hose supplies the compressed gas to the internal components of the motor. The outer hose captures the exhausted gas from the internal components of the motor and transports this exhaust gas to the diffuser section of the lubricant diffuser cartridge located on the foot control end of the hose at floor level. This self-contained lubricant/diffuser system consists of two components; a permanently attached receptor base on the foot control connector section of the hose and a disposable lubricant/diffuser cartridge. The cartridge provides two functions; the lubrication for the internal components of the motor and the capture of the exhausted gas from the motor. The foot or finger controller is used to activate the flow of compressed air or nitrogen (gas) into the pneumatic motor and is connected to the pressure regulator of the gas supply system through the regulator hose. The Midas Rex MR7 Pneumatic High Speed System is intended to be used with all existing Midas Rex Legend attachments and dissecting tools previously cleared through K020069.

Indication for Use: The Medtronic Midas Rex MR7 System is a pneumatically operated surgical instrument system. The pneumatic motors provides power to operate removable rotating surgical 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.

Predicate Device Identification: The Medtronic Midas Rex MR7 System is substantially equivalent to the following predicate device:

- Midas Rex Legend System - K020069

Comparison to Predicate Device: The Midas Rex MR7 System is similar in device design, function, intended use and fundamental scientific technology to the previously cleared Midas Rex Legend System (K020069). It should be noted that the indications for use remain identical to those cleared under K020069.

Test Data: Laboratory bench testing conducted on the Midas Rex MR7 System demonstrates substantially equivalent performance characteristics to the predicate Midas Rex Legend System cleared under K020069.

Summary: Based upon the laboratory bench test summaries, intended use, and the successful completion of design control activities; the Midas Rex MR7 System has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2009

Medtronic Powered Surgical Solutions
Jeffrey Henderson
Vice President, Quality & Regulatory affairs
4620 North Beach Street
Fort Worth, TX 76137

Re: K090112
Trade/Device Name: Medtronic Midas Rex MR7 Pneumatic System
Regulation Number: 21 CFR 882.4370
Regulation Name: Pneumatic cranial drill motor
Regulatory Class: Class II
Product Code: HBB
Dated: December 19, 2008
Received: January 16, 2009

Dear Mr. Henderson:

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

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

Indications for Use

510(k) Number (if known): K090112

Device Name: Medtronic Midas Rex MR7 Pneumatic High Speed System

Indications for Use:

The Medtronic Midas Rex MR7 System is a pneumatically operated surgical instrument system. The pneumatic motors provide 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 ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K090112