LEGEND® Power Adapter
510(k) Summary

August 2010

AUG 2 4 2010

I. **Company:**

Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact:

Jennifer Hackney
Regulatory Affairs Specialist

II.

Proposed Proprietary Trade Name:	LEGEND® Power Adapter
Common Name:	Power Adapter
Classification Name(s):	Surgical instrument motors and accessories/attachments;
Classification:	Class II
Product Code(s):	HBC
Regulation No.:	882.4360
Predicate Device:	MIDAS REX® LEGEND® System Perforator Attachment

III. Description:

The LEGEND® Power Adapter is a stainless steel adapter that can be used with the MIDAS REX® LEGEND® System to provide power to MEDTRONIC rotating surgical cutting tools. The LEGEND® Power Adapter provides a 20:1 gear ratio reduction when used with the MIDAS REX® LEGEND® System.

IV. Indications for Use:
The LEGEND® Power Adapter is intended to be used with the MIDAS REX® LEGEND® System. When the LEGEND® Power Adapter is attached to the MIDAS REX® LEGEND® System, the MIDAS REX® LEGEND® System motors provide power to operate removable rotating surgical cutting tools and their accessories intended for 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.

V. Technological Characteristics:
The LEGEND® Power Adapter is a stainless steel adapter that can be used with the MIDAS REX® LEGEND® System to provide power to MEDTRONIC rotating surgical cutting tools. Both products are manufactured from stainless steel, utilize gears to reduce the output of the MIDAS REX® LEGEND® System, and are provided non-sterile for end user steam sterilization.

VI. Substantial Equivalence:
Documentation was provided demonstrating that the LEGEND® Power Adapter is substantially equivalent to other commercially available accessories, including those included in the MIDAS REX® LEGEND® System.

Dynamometer testing was performed to confirm that the LEGEND® Power Adapter would function appropriately when attached to the MIDAS REX® LEGEND® Power Systems. The subject adapter successfully met the acceptance criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA
% Ms. Theresa Leister
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

AUG 2 4 2010

Re: K101168
Trade/Device Name: LEGEND® Power Adapter
Regulation Number: 21 CFR 882.4370
Regulation Name: Pneumatic cranial drill motor
Regulatory Class: Class II
Product Code: HBB, GET
Dated: August 18, 2010
Received: August 20, 2010

Dear Ms. Leister:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101168

510(k) Number (if known): K101168

Device Name: LEGEND® Power Adapter

Indications for Use:

The LEGEND® Power Adapter is intended to be used with the MIDAS REX® LEGEND® System. When the LEGEND® Power Adapter is attached to the MIDAS REX® LEGEND® System, the MIDAS REX® LEGEND® System motors provide power to operate removable rotating surgical cutting tools and their accessories intended for 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR Over-The-Counter Use _____

Per 21 CFR 801.109

Neil R Ogden for mkm

(Division Sign-Off)

Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K101168