K062849

SECTION II

Required Elements for all 510(k) submissions: General Information

A. Device Name (Unmodified):

Device Trade Name
Smith & Nephew DYONICS Power II Shaver System

JAN 19 2007

Common/Classification Name
Arthroscopic Accessory – Shaver Control Unit

B. Submitter Information:

Company Name	Smith & Nephew, Inc., Endoscopy Division
Address	150 Minuteman Road, Andover, MA, 01810
Contact	Kathleen Burns

C. Establishment Registration Number(s):

Owner/Operator Name	Smith & Nephew, Inc. Endoscopy Division
Address	150 Minuteman Road, Andover, MA 01810
Establishment Registration #	ER# 1216828
Owner Operator #	# 1216828
Manufacturing Site	Smith & Nephew, Inc. Endoscopy Division
Address	76 S.Meridian Ave. Oklahoma City, OK 73107
Establishment Registration #	ER# 1643264
Owner Operator #	# 1216828

D. Device Classification: Regulation Number and Regulatory Status

The Smith & Nephew DYONICS Shaver System has been classified as Class II, per 21 CFR §888.1100 and 874.4250. The device Procode is HRX, ERL.

E. Performance Standards

There are no known performance standards or special controls promulgated under section 514 of the Act for this device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
% Ms. Kathleen Burns
Regulatory Specialist
150 Minuteman Road
Andover, Massachusetts 01810

JAN 19 2007

Re: K062849
Trade/Device Name: Smith & Nephew DYONICS Power II Shaver System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: December 18, 2006
Received: December 20, 2006

Dear Ms. Burns:

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 Office of Compliance at (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Smith & Nephew DYONICS Power II Shaver System

Indications for Use:

The Smith & Nephew DYONICS Power II Shaver System control unit is indicated for use, when used with appropriate procedure specific blades, for resection of soft and osseous tissues including, but not limited to, use in large articular cavities, small articular cavities, and Functional Endoscopic Sinus Surgery (FESS). The FESS application is limited to those small blades which are appropriate for the procedure.

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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062847