K030196

Endoscopy Division

Smith & Nephew, Inc.
150 Minuteman Road, Andover, MA 01810-1031 U.S.A.
Telephone: 978-749-1000
Fax: 978-749-1599

FEB 2 0 2003

Smith+Nephew

Exhibit H

510(k) Summary
Dyonics® Power-HERMES READY™
Date Prepared: January 20, 2003

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Janice Haselton
Regulatory Affairs Specialist II

C. Device Name

Trade Name:	Dyonics® Power-HERMES READY™
Common Name:	Power control unit
Classification Name:	Ear, Nose, and throat electric or pneumatic surgical drill and Arthroscopes and Accessories

D. Predicate Devices

The Smith & Nephew Dyonics® Power-HERMES READY™ Control Unit is substantially equivalent in design, materials, function and intended use to the following devices in commercial distribution: Dyonics ® Power Control Unit

E. Description of Device

The Dyonics® Power-HERMES READY™ control unit is is an electro-mechanical device containing systems, controls, and indicators which provides electrical power to motorized hand pieces and accessories for resection of soft and osseous tissue in arthroplasty, synovectomy and intraarticular cutting and shaving. The control unit allows a surgeon to set the blade speed within minimum and maximum speeds programmed for each blade type. The Dyonics® Power-HERMES READY™ control unit incorporates a communication interface for voice activation with the HERMES™ control center. When connected to the HERMES™ control center, the control unit may be voice activated or activated manual by use of a hand held pendant.

F. Intended Use

The Dyonics® Power –HERMES READY™ 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.

G. Comparison of Technological Characteristics

The Dyonics Power®–HERMES READY™ has the same technological characteristics and intended use as the predicate device, Dyonics Power®. The addition of a communication interface for voice activation with the HERMES™ control center offers the surgeon direct communication with the device without changing the intended use or features of the Dyonics Power control unit.

The Dyonics Power®–HERMES READY™ will be tested with the following domestic and international standards:

- UL 2601-1: Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1: Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety + Amendments1 and 2
- IEC 60601-1-1: Medical Electrical Equipment General Requirements for Safety 1, Collateral Standard: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2: Medical Electrical Equipment General Requirements for Safety2, Collateral Standard: Electromagnetic Compatibility- Requirements and Tests
- CAN/CSA – C22.2 No. 601.1-M90- Medical Electrical Equipment General Requirements for Safety: A National Standard for Canada

Janice Hasselton

Regulatory Affair Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2003

Ms. Janice Haselton
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
150 Minuteman Road
Andover, Massachusetts 01810-1031

Re: K030196
Trade Name: Dyonics Power Control Unit
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: January 20, 2003
Received: January 21, 2003

Dear Ms. Haselton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 (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

Exhibit B

Indications for Use Statement

510(k) Number (if known) K030196

Device Name Dyonics® Power-HERMES READY™

Indications for Use

The Dyonics® Power–HERMES READY™ 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

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

510(k) Number K630196