

MAR 13 2000

510(k) Summary – K994365
Dyonics ElectroBlade
Date Prepared: January 17, 2000

Endoscopy Division

Smith & Nephew, Inc.
160 Dascomb Road, Andover, MA 01810 U.S.A.
Telephone: 978-749-1000
Telefax: 978-749-1599

Smith+Nephew

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
160 Dascomb Road
Andover, MA 01810

B. Company Contact

Deborah Connors
Principal Regulatory Affairs Specialist

C. Device Name

Trade Name: Dyonics ElectroBlade
Common Name: Arthroscopic Surgery Blade/Electrosurgical Probe
Classification Name: Electrosurgical Probe

D. Predicate Devices

The Dyonics ElectroBlade is substantially equivalent in design, materials, function and intended use to the following devices in commercial distribution: Dyonics Arthroscopic Surgery Blades, Dyonics Electrosurgical Switchpen and Probes.

E. Description of Device

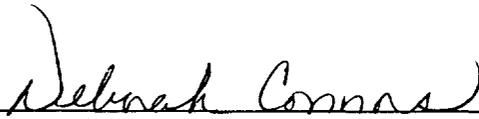
The Dyonics ElectroBlade combines the rotary cutting technology of Dyonics Arthroscopic Surgery Blades with the electrosurgical capabilities of a monopolar electrosurgery probe. The inner rotational blade is electrified by connection to a standard electrosurgical generator. Insulation on the outer blade isolates the electrical energy to the inner tube where it is exposed to tissues at the cutting window of the blade. The Dyonics ElectroBlade operates in conjunction with the standard Dyonics shaver system and standard monopolar electrosurgical generator systems. The Dyonics ElectroBlade requires the use of an electrosurgical dispersive pad.

F Intended Use

The Dyonics ElectroBlade is indicated for use in arthroscopic surgical procedures of large and small articular cavities for resection and excision of soft and osseous tissues and for coagulation of bleeding.

G Comparison of Technological Characteristics

The Dyonics ElectroBlade combines the technologies of the Dyonics Arthroscopic Surgery Blade and the Dyonics Electrosurgical Switchpen and Probe. Technologies, design, materials of construction and intended uses are similar for these devices. This combination of existing technologies presents no new risks to the patient or user of this device.



Deborah Connors
Principal Regulatory Affairs Specialist



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Deborah Connors
Principal Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, Massachusetts 01810

Re: K994365
Trade Name: Dyonics ElectroBlade
Regulatory Class: II
Product Code: GEI
Dated: December 23, 1999
Received: December 27, 1999

Dear Ms. Connors:

We have reviewed your Section 510(k) 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). 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 (Premarket Approval), 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 895.

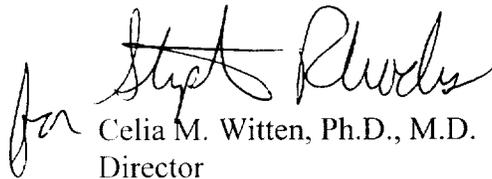
A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for *Celia M. Witten*

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

Enclosure

510(k) Number : K994365

Device Name : Dyonics ElectroBlade

Indications for Use :

The Dyonics ElectroBlade is indicated for use in arthroscopic surgical procedures of large and small articular cavities for resection and excision of soft and osseous tissues and for coagulation of bleeding.

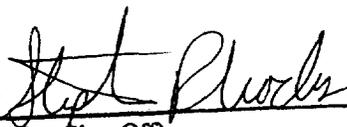
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR Over-the-Counter

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994365