K012314

510(k) Summary FEB 01 2002
DYONICS ElectroBlade Resector™
Date Prepared: July 20, 2001

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

Tim Crabtree
Regulatory Affairs Specialist

C. Device Name

Trade Name: DYONICS EletroBlade Resector
Common Name: Arthroscopic Surgery Blade / Electrosurgical Probe
Classification Name: Electrosurgical Probe

D. Predicate Devices

DYONICS ElectroBlade (K994365)

E. Description of Device

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

D. Intended Use

The DYONICS Electroblade Resector is indicated for use in arthroscopic surgical procedures of large and small articular cavities. The DYONICS Electroblade Resector is effective in soft and osseous tissue resection and in hemostasis of bleeding vessels. It is intended for arthroscopic procedures using saline solution, Ringer's lactate or other conductive solutions as an irrigant under direct or video assisted fiberoptic visualization.

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E. Comparison of Technological Characteristics

The DYONICS Electroblade Resector is a combination of both bipolar RF and mechanical resector technologies. The design reflects this combination of these technologies. The resection and coagulation capabilities are features that are also found in the DYONICS Electroblade. The modified DYONICS Electroblade Resector is substantially equivalent to the DYONICS Electroblade in intended use, materials and method of operation.

Tim Crabtree

Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 01 2002

Mr. Tim Crabtree
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, Massachusetts 01810

Re: K012314
Trade/Device Name: DYONICS Electroblade Resector™
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulating device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 2, 2001
Received: November 5, 2001

Dear Mr. Crabtree:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

510(k) Number : K012314

Device Name: DYONICS Electroblade Resector™

Indications for Use:

The DYONICS Electroblade Resector is indicated in arthroscopic surgical procedures of large and small articular cavities for resection and excision of soft and osseous tissues. The DYONICS EletroBlade Resector is effective in tissue resection and hemostasis of bleeding vessels. It is intended for arthroscopic procedures using saline solution, Ringer's lactate or other conductive solutions as an irrigant under direct or video-assisted fiber-optic visualization.

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number K012314