

JUL 27 2004

 We are smith&nephew

Page ① of 3

SECTION IV

K041328

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Date Prepared: May 19, 2004

A. Submitter's Name:

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

B. Company Contact:

Karen Provencher
Regulatory Affairs Specialist
Phone: 978-749-1365
Fax: 978-749-1443

C. Device Name

Trade Name: Smith & Nephew ElectroBlade[®] Resector
Smith & Nephew ElectroBlade[®] Adaptor

Common Name: Arthroscopic Surgery Blade and Electrosurgical Probe

Classification Name: Electrosurgical cutting and coagulation device

D. Predicate Devices

The Smith & Nephew Smith & Nephew ElectroBlade[®] Resector and Smith & Nephew ElectroBlade[®] Adaptor combination is substantially equivalent in intended use and fundamental scientific technology to the following legally marketed devices in commercial distribution: Smith & Nephew ElectroBlade[®] Resector and ERBE ICC 350. The predicate device combination was cleared in K031675 on June 20, 2003.

E. Description of Device

The Smith & Nephew ElectroBlade[®] Resector combines electrosurgical and shaver technology to provide hemostasis and mechanical cutting in a single instrument. The Smith & Nephew ElectroBlade[®] Adaptor is a transformer that converts the power output of the generator into a higher current / lower voltage output.

F. Intended Use

The Smith & Nephew ElectroBlade Adaptor, when used in conjunction with the Smith & Nephew ElectroBlade[®] Resector is indicated in arthroscopic surgical procedures of large and small articular cavities for resection and excision of soft tissue. The Smith & Nephew ElectroBlade[®] 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.

G. Comparison of Technological Characteristics

The Smith & Nephew Smith & Nephew ElectroBlade[®] Resector and Smith & Nephew ElectroBlade[®] Adaptor combination is substantially equivalent in design, materials, function and intended use to the following legally marketed devices in commercial distribution: Smith & Nephew ElectroBlade[®] Resector and ERBE ICC 350. The predicate device combination was cleared in K031675 on June 20, 2003.

H. Summary Performance Data

The proposed device combination will perform as well as the predicate device combination to the following standards at the time of commercialization:

- ANSI/AAMI HF18-1993 for Electrosurgical Devices
- IEC 601-1(A1 + A2) Medical Electrical Equipment: Part 1 General Requirements for Safety

- IEC 601-1-2 Medical electrical equipment - Part1: General Requirements for Safety and Part 2: Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC60601-2-2:1998 for Medical Electrical Equipment (Part2-2): Particular Requirements for the Safety of High Frequency Surgical Equipment.

The Smith & Nephew ElectroBlade[®] Resector referenced in this submission is the same as the resector cleared in K012314. This resector is in compliance with the following standards:

- ANSI/AAMI ISO 10993-1 for Biological evaluation of medical devices - Part1: Guidance on selection of tests
- ANSI/AAMI ISO 11135 Validation and Routine control of Ethylene Oxide Sterilization



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2004

Ms. Karen Provencher
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
150 Minuteman Road
Andover, Massachusetts 01810

Re: K041328

Trade/Device Name: Smith & Nephew ElectroBlade™ Resector
Smith & Nephew ElectroBlade™ Adaptor

Regulation Number: 21 CFR 878.4400, 21 CFR 888.1100

Regulation Name: Electrosurgical cutting and coagulation device and accessories;
Arthroscope

Regulatory Class: II

Product Code: GEI, HRX

Dated: May 19, 2004

Received: May 19, 2004

Dear Ms. Provencher:

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.

Page 2 - Ms. Karen Provencher

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

Indications for Use

510(k) Number (if known): K041328

Device Name: Smith & Nephew ElectroBlade® Resector and Smith & Nephew ElectroBlade® Adaptor

Indications For Use:

The Smith & Nephew ElectroBlade Adaptor, when used in conjunction with The Smith & Nephew ElectroBlade® Resector is indicated in arthroscopic surgical procedures of large and small articular cavities for resection and excision of soft tissue. The Smith & Nephew ElectroBlade® 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.

Prescription Use X

OR

Over-The-Counter Use _____

(Per 21 CFR 801.109)

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

Miriam C. Provost
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K041328