

OCT 29 2003

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SECTION IV

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: July 31, 2003

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 TriVex™ System
Common Name: Varicose Vein Ablation System
Classification Name: Stripper, Vein, External

D. Predicate Devices

The Smith & Nephew TriVex™ System is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: The Dyonics® Varicose Vein Ablation System - K990723, Subcutaneous Illuminator - K991323, Smith & Nephew Xenon Light Source - K994084, and H.K. Surgical Klein Pump - K012044.

E. Description of Device

The Smith & Nephew TriVex™ System consists of a control unit mounted on a pedestal stand, dual peristaltic pumps, an illuminator, resector handpiece and footswitches.

F. Intended Use

The proposed Smith & Nephew TriVex™ System is indicated for use in ambulatory phlebectomy procedures for the resection and ablation of varicose veins.

G. Comparison of Technological Characteristics

The Smith & Nephew TriVex™ System is substantially equivalent in design, materials, function and intended use to the following devices cleared for commercial distribution:

- The Dyonics® Varicose Vein Ablation System - K990723
- Subcutaneous Illuminator - K991323
- Smith & Nephew Xenon Light Source - K994084
- H.K. Surgical Klein Pump - K012044

G. Summary Performance Data

The Smith & Nephew TriVex™ System meets the biocompatibility requirements of ISO 10993-1 and electrical safety standards for BF type equipment as stated in UL 60601-1 and IEC 60601-1.



OCT 29 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K032387

Trade/Device Name: Smith & Nephew TriVex™ System
Regulation Number: 21 CFR 870.4885
Regulation Name: External vein stripper
Regulatory Class: II
Product Code: DWQ
Dated: July 31, 2003
Received: August 4, 2003

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.

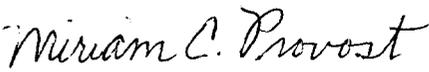
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,


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): K032387

Device Name: Smith & Nephew TriVex™ System

Indications For Use:

Indicated for use in ambulatory phlebectomy procedures for resection and ablation of varicose veins.

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

510(k) Number K 632387

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____