K041453

JUL 22 2004

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

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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: May 28, 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 Tumescent Catheter Inversion System
Common Name:	External Vein Stripper
Classification Name:	External Vein Stripper

D. Predicate Devices

The Smith & Nephew Tumescent Catheter Inversion System is substantially equivalent in intended use and fundamental scientific technology to the following

legally marketed device in commercial distribution: Codman® Disposable Vein Stripper (pre-amendment device).

E. Description of Device

The Smith & Nephew Tumescent Catheter Inversion System provides a system for removal of incompetent greater saphenous veins. The system also provides the capability to flush the tunnel left behind from the removal of the vein with tumescent solution.

F. Intended Use

The Smith & Nephew Tumescent Catheter Inversion System is intended to provide a system for removal of incompetent greater saphenous veins.

G. Comparison of Technological Characteristics

The Smith & Nephew Tumescent Catheter Inversion System is substantially equivalent in design, materials, function and intended use to the following device cleared for commercial distribution: Codman® Disposable Vein Stripper – legally marketed preamendment device.

H. Summary Performance Data

There are no known performance standards or special controls promulgated under section 514 of the Act for this device. This device has been tested and found to be in compliance with ISO 10993-1 and at the time of commercialization will be in compliance with applicable sterilization standards. This device has been tested and found to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2004

Smith & Nephew, Inc.
c/o Ms. Karen Provencher
Regulatory Affairs Specialist
150 Minuteman Road
Andover, MA 01810

Re: K041453
Tumescent Catheter Inversion System
Regulation Number: 21 CFR 870.4885
Regulation Name: External Vein Stripper
Regulatory Class: Class II (two)
Product Code: DWQ
Dated: May 28, 2004
Received: June 1, 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.
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) 594-4646. 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041453

Device Name: Smith & Nephew Tumescent Catheter Inversion System

Indications For Use:

The Smith & Nephew Tumescent Catheter Inversion System is intended to provide a system for removal of incompetent greater saphenous veins.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Richey

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041453