

OCT 5 1999

K990723

510(k) Summary
March 3, 1999
Smith & Nephew, Inc., Endoscopy Division
Dyonics Varicose Vein Ablation Blade

Endoscopy Division

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

Smith+Nephew

Substantial Equivalence:

The Dyonics Varicose Vein Ablation Blade is substantially equivalent in intended use and procedural outcomes to the conventional phlebectomy hook as supported by the clinical experience submitted with this Premarket Notification Submission. Patient contacting materials for both devices are surgical stainless steel.

Predicate Device:

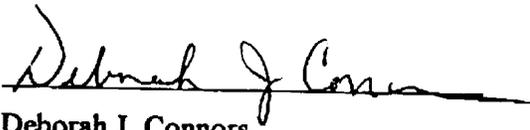
The predicate device for the intended use described in this submission is the Medicon Ambulatory Phlebectomy Hook.

Summary of Device Function:

The design of the blades offers required precision for varicose vein ablation by controlling the location and extent of tissue resection. Target tissue is drawn into the cutting window of the blade under suction while the rotating inner blade shears off the tissue. The location and extent of tissue removal is completely controlled by surgeon placement and rotary activation of the blade.

Intended Use of Device:

The Dyonics Varicose Vein Ablation Blade (*proprietary name TBD*) is indicated for use in ambulatory phlebectomy procedures for the resection and ablation of varicose veins.



Deborah J. Connors
Senior Regulatory Affairs Specialist



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 1999

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

Re: K990723
Trade Name: Dyonics Varicose Vein Ablation Blade
Regulatory Class: II
Product Code : GEI
Dated: June 30, 1999
Received: July 6, 1999

Dear Ms. Connors:

This letter corrects our substantially equivalent letter of October 5, 1999, regarding the Product Code.

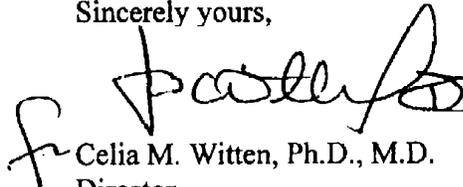
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

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- 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 that 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 their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and "W".

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 : K 990723

Device Name : Dyonics Varicose Vein Ablation Blade

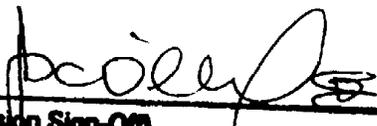
Indications for Use :

The Dyonics Varicose Vein Ablation Blade (*proprietary name TBD*) is indicated for use in ambulatory phlebectomy procedures for the resection and ablation of varicose veins.

(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)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990723