K061373

510 (k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: 15 May 2006

AUG 0 1 2006

510(k) number: _____

Applicant Information:
VNUS Medical Technologies, Inc.
5799 Fontanoso Way
San Jose, CA 95138

Contact Person: Carelle Karimimanesh
Phone Number: (408) 360-7261
Fax Number: (408) 365-8480

Device Information:

Classification:	Class II
Trade Name:	VNUS® Closure*FAST*™ Catheter
Classification Name:	Electrosurgical Device (21 CFR §878.4400)

Equivalent Device:
The subject device is substantially equivalent in intended use and/or method of operation to the VNUS® ClosurePlus™ Catheter (K030557).

The technological characteristics and principals of operation of the VNUS ClosureFAST catheter are substantially equivalent to the noted predicate device. Both devices rely on the delivery of RF energy to an intravascular catheter that heats a blood vessel to a specific temperature to achieve the intended use.

Intended Use:
The VNUS® *ClosureFAST*™ Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

Test Results:
Performance
Results of *in vitro* testing demonstrate that the VNUS ClosureFAST catheter is substantially equivalent to the predicate device effective for its intended function.

Biocompatibility
The materials used in the VNUS Closure*FAST* Catheters have been shown to be biocompatible.

Summary:
Based on the intended use, product performance, and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 1 2006

VNUS Medical Technologies, Inc.
% Carelle Karimimanesh
Director, Regulatory Affairs
2200 Zanker Road, Suite F
San Jose, California 95131

Re: K061373
Trade/Device Name: VNUS® *Closure*FAST™
Regulatory Number: 21 CFR 878.4400
Regulatory Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 15, 2006
Received: May 17, 2006

Dear Carelle Karimimanesh:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: VNUS® *ClosureFAST™* Catheter

510(k) Number: K061373

Indications for Use:

The VNUS® *ClosureFAST™* Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

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Prescription Use:
(21 CFR §801 Subpart D)

or

Over the Counter Use:
(21 CFR §801 Subpart C)

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Barbara Burlington

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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