Summary of Safety and Effectiveness

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A. Determination of Substantial Equivalence

VNUS RFS and RFS*Flex* devices

B. Common Name

Bipolar Electrosurgical Instrument

C. Predicate Device(s)

VNUS® Closure® System (K982816, K003092, and K030557); and

VNUS® Vessel and Tissue Coagulation System (proprietary name: TBD) (K033547)

D. Device Description

The VNUS RFS family of devices is a bipolar, high frequency electrosurgical system designed for use in general surgical procedures where blood vessel and tissue coagulation is desired. These devices are compatible with separately cleared Radiofrequency (RF) Generator, and the Instrument Cable manufactured by VNUS Medical Technologies.

The VNUS RFS family of devices are sterile disposable devices intended for a single-use only. The device's function is to deliver bipolar RF energy to the desired treatment site and relay temperature and other feedback to the RF Generator. The disposable device is available in 2 bipolar configurations and multiple lengths for selection by the physician based on preference for method of vessel access, location and length of the vessel to be treated. This submission reflects a name change, minor modification of the indication statement (more specific inclusion of perforator and tributary veins), and minor design changes.

E. Intended Use

The VNUS RFS and RFS*Flex* Devices are intended for use in vessel and tissue coagulation including:

- Treatment of incompetent (i.e., refluxing) perforator and tributary veins

F. Intended Use of Predicate Devices

The specified predicate devices are indicated for "coagulation of blood vessels in patients with superficial vein reflux" (VNUS Closure System) and "vessel and tissue coagulation" (VNUS Vessel and Tissue Coagulation System).

G. Technological Comparison

RF energy has been widely used in electrosurgical equipment for many years. The safety and efficacy of such devices has been well established for a variety of intended uses. The use of bipolar RF energy delivery has potential advantages over monopolar systems. No grounding pads are required, and the potential for damage to adjacent tissue is minimized, as the patient is no longer the return path for electrical current. The efficiency of bipolar RF energy delivery allows systems such as the VNUS RF Generator to be used at lower voltage and power settings as compared with monopolar systems.

The technological characteristics and principals of operation of the VNUS RFS family of devices are substantially equivalent to the noted predicate devices. All devices rely on the delivery of RF energy to achieve their intended use.

H. Discussion of Clinical/Non-Clinical Tests and Conclusions

Performance
Results of in-vitro testing demonstrate that the VNUS RFS and RFS*Flex* devices are safe and effective for their intended function.

Biocompatibility
The materials used in the VNUS RFS and RFS*Flex* Devices have been shown to be biocompatible.

I. Summary of Safety and Effectiveness

Based upon the intended use, design, materials, function, comparison with currently marketed devices and the non-clinical testing it is concluded that the VNUS RFS and RFS*Flex* Devices are substantially equivalent to the noted predicate devices. The RF ablation/coagulation of blood vessels (i.e., VNUS Closure) has a well-established history of safe an efficacious use in over 100,000 procedures.

Brady Esch
Directory, R&D
VNUS Medical Technologies, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2005

VNUS Medical Technologies, Inc.
c/o Sam Nanavati
750 Chesapeake Drive
Redwood City, California 94063

Re: K052003
Trade/Device Name: VNUS® RFS and RFS Flex Devices
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 22, 2005
Received: July 25, 2005

Dear Mr. Nanavati:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

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

Enclosure

Device Name:
VNUS® RFS and RFS*Flex* Devices

510(k) Number (if known): K052003

Indications for Use:

The VNUS RFS and RFS*Flex* devices are intended for use in vessel and tissue coagulation including:

- Treatment of incompetent (i.e., refluxing) perforator and tributary veins

Over the Counter Use:
(Per 21 CFR 801.109)

or

Prescription Use: X

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

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

510(k) Number K052003