JUN - 7 2004

SUMMARY OF SAFETY AND EFFECTIVENESS

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: March 1, 2004

510(k) number: K040638

Applicant Information:
VNUS Medical Technologies, Inc.
2200 Zanker Avenue, Suite F
San Jose, CA 95131

FDA Registration Number: 2953189

Contact Person
Sam Nanavati
Phone Number: (408) 473-1140
Fax Number: (408) 944-0292

Device Information:
Classification: Class II
Trade Name: VNUS Radiofrequency Generator, Model RFG2
Classification Name: Electrosurgical Device

Predicate Device(s)
VNUS RF Generator models RF-110 and RF-220 cleared as a part of the VNUS® Closure® System (K982816, K003092, and K030557), and VNUS Vessel and Tissue Coagulation System (K0033547)

Device Description:
The VNUS RF Generator, model RFG2 is a bipolar, high frequency electronic, microprocessor / software controlled instrument. It allows the user to set Power, Temperature and Time values, and provides user displays of Power, Temperature and Time (set-points and measured values) as well as measured Impedance and user messages. The RF Generator remains out of the sterile field during use, and is provided non-sterile.

The model RFG2 is compatible only with the disposable RF delivery devices (e.g., catheters) designed, manufactured and marketed by VNUS Medical Technologies under separate clearance(s).

The instrument cable connects the disposable device to the RF generator. The Instrument Cable is provided non-sterile, and is user sterilizable by autoclave. It has been validated to multiple steam sterilization cycles. Both ends of the cable are identical to eliminate connection errors. If the VNUS RF delivery device has an integrated cable, a separate instrument cable is not necessary.

Intended Use:
The VNUS Radiofrequency Generator is intended for use with VNUS radiofrequency devices intended for vessel and tissue coagulation.

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).

Technological Comparison
The RF energy is 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 RF Generator, model RFG2 are substantially equivalent to the noted predicate devices.

Test Results:
Performance
Results of in-vitro testing will demonstrate that the VNUS Radiofrequency Generator is safe and effective for its intended use.

Summary of Safety and Effectiveness
Based upon the design, materials, function, intended use, comparison with currently marketed devices and the non-clinical testing performed by VNUS, it is concluded that the VNUS Radiofrequency Generator, Model RFG2 (proprietary name: TBD) is substantially equivalent to the noted predicate devices in safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2004

Mr. Sam Nanavati
Director, Quality and Regulatory Affairs
VNUS Medical Technologies, Inc.
2200 Zanker Road, Suite F
San Jose, California 95131

Re: K040638
Trade/Device Name: VNUS Radiofrequency Generator, Model RFG2
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 8, 2004
Received: March 10, 2004

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 (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,

Miriam C. Provost

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): K040638

Device Name: **VNUS Radiofrequency Generator, Model, RFG2**

Indications for Use:

The VNUS Radiofrequency Generator is intended for use with VNUS radiofrequency devices intended for vessel and tissue coagulation.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

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