3/17/99

K982816

Appendix D:

Summary of Safety and Effectiveness

Summary of Safety and Effectiveness

A. Determination of Substantial Equivalence

VNUS® Closure™ System

B. Common Name

Electrosurgery System/Electrosurgical Coagulator

C. Predicate Device(s)

Cameron-Miller Vein Eraser System (Pre-enactment)
VNUS® Closure™ System (K974521)

D. Device Description

The VNUS Closure System consists of three main components: The VNUS Closure Catheter, the VNUS RF Generator and the VNUS Instrument Cable. The Closure Catheter is provided sterile, and is a single-use, disposable device. The RF Generator is non-sterile. The Instrument Cable is autoclave sterilized by the user. An optional Footswitch for RF ON/RF OFF is provided for use at the physician's discretion.

The RF Generator is a high frequency (460kHz) electronic, bipolar, microprocessor / software controlled instrument. It allows the user to set Power, Temperature and Time values, and provides user displays of Power, Temperature and Time (setpoints and measured values) as well as measured Impedance and user messages. Audible tones provide additional feedback to the physician. The RF Generator acts to maintain the set temperature by regulating the power delivered up to the maximum set power. By doing so, the RF Generator controls the temperature at the tip of the catheter.

The Closure Catheter is used to provide RF energy to the desired treatment site and relay temperature feedback to the RF Generator. It is designed to deliver the RF energy in a bipolar manner.

The Instrument Cable is used to connect the Closure Catheter to the RF Generator.

E. Intended Use

The VNUS Closure System is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

F. Intended Use of Predicate Devices

The specified predicate devices are indicated for "coagulation of blood vessels in patients with superficial vein reflux" and "ablation and coagulation of blood vessels during general surgical procedures."

G. Technological Comparison

The technological characteristics and principals of operation of the VNUS Closure System 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

Clinical/Non-Clinical tests performed by VNUS have demonstrated the substantially equivalent performance of the Closure System with predicate electrosurgery systems used for substantially equivalent indications.

I. 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 Closure System is substantially equivalent to the noted predicate devices in safety and effectiveness.

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John D'Angelo
Vice President, Quality Assurance and Compliance
VNUS Medical Technologies, Inc.
August 7, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 1999

Mr. John D'Angelo
Vice President, Quality Assurance and Regulatory Affairs
VNUS Medical Technologies, Inc.
238 E. Caribbean Dr.
Sunnyvale, CA 94089

Re: K982816
Trade Name: VNUS® Closure™ System
Regulatory Class: II
Product Code: GEI
Dated: December 8, 1998
Received: December 17, 1998

Dear Mr. D'Angelo:

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 (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). 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.

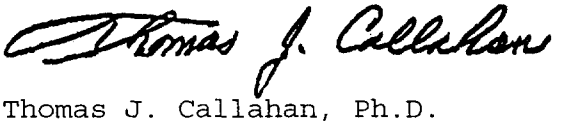
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Closure™ System 510(k) Number (if known):

Indications for Use:

The VNUS® Closure™ System is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Over the Counter Use: **or** **Prescription Use:** ✓
(Per 21 CFR 801.109)

for TJC

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number