K031358

SUMMARY OF SAFETY AND EFFECTIVENESS

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

1. Submitter's name, address, telephone number, contact person, and date summary prepared:

a. Submitter:
Vascular Control Systems, Inc.
32236 Paseo Adelanto, Ste. E
San Juan Capistrano, CA 92675
(949) 488-8700

b. Contact Person:
Kathleen Roberts
Senior Regulatory Affairs Specialist
Telephone: (949) 488-8700 ext. 115
Fax: (949) 488-8708

c. Date Summary Prepared: April 18, 2003

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: Transvaginal Doppler Probe

b. Classification name: Diagnostic Ultrasonic Transducer
(21 CFR §892.1570)

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company:	Vascular Control Systems, Inc.
Device:	Transvaginal Doppler Probe
510(k):	K023024
Date Cleared:	September 26, 2002

4. A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The Transvaginal Doppler Probe is a ring-handled instrument with integrated Doppler sensors, which allow for bilateral blood flow sensing of the uterine blood vessels by connecting to a commercially available portable transceiver box. The Transvaginal Doppler Probe is manufactured from stainless steel.

5. Statement of intended use:

The Transvaginal Doppler Probe is intended for bilateral detection of uterine blood vessels.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

The Transvaginal Doppler Probe and the predicate device are both intended to detect blood flow of blood vessels using an 8 MHz pulsed-wave Doppler sensor. The Doppler crystals in both devices are located at the distal end to allow for forward detection of blood flow. Both devices are constructed of stainless steel.

7. Brief summary of nonclinical tests and results:

The Transvaginal Doppler Probe has been designed and tested to comply with the requirements of IEC 60601-1 for electrical and thermal safety. Acoustic output power measurements were performed in accordance with the FDA Guidance document *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*. Test results indicate reliable performance when the device is used in accordance with the Instructions for Use. The Transvaginal Doppler Probe does not raise new issues of safety, effectiveness, or performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2003

Vascular Control Systems, Inc.
% Mr. Heinz Joerg Steneberg
Responsible Third Party
TUV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K031358
Trade Name: Transvaginal Doppler Probe,
Models # 09-0012-01, 09-0012-02, and 09-0012-03
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 ITX
Dated: April 28, 2003
Received: April 30, 2003

Dear Mr. Steneberg:

We have reviewed your Section 510(k) premarket 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Vascular Technologies Doppler Transceiver (8 MHz selectable channel, P/N 108900) as described in your premarket notification:

Transducer Model Number

09-0012-01
09-0012-02
09-0012-03

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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your 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 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) 594-4591. 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" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal				P						
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: Model # 09-0012-01, 09-0012-02, 09-0012-03

The transducer is specified for use with the Vascular Technology, Inc. Doppler Transceiver, 8 MHz Selectable Channel, VTI P/N 108900

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031358