

FEB - 9 2004

Vascular Control Systems, Inc.
510(k) K032125 - Amendment 1
August 19, 2003 - Cstat

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-E Paseo Adelanto
San Juan Capistrano, CA 92675
(949) 488-8700
- b. Contact Person: Kathleen Roberts
Sr. Regulatory Affairs Specialist
Telephone: (949) 488-8700 ext. 115
Fax: (949) 488-8708
- c. Date Summary Prepared: August 19, 2003

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

- a. Trade/Proprietary Name: Cstat
- b. Classification name: Vascular Clamp

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: VCS-A Clamp
510(k): K023154
Date Cleared: December 20, 2002

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

Company: Medical Designs LLC
Device: Hand Drill
510(k): K022712
Date Cleared: November 12, 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 Cstat is a ring-handled instrument with integrated Doppler sensor, which allows for blood flow sensing of blood vessels by connecting to a commercially available portable transceiver box. The Cstat is manufactured from nylon and polycarbonate.

5. Statement of intended use:

The Cstat is intended for detection and temporary occlusion of blood vessels.

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

The Cstat and the predicate VCS-A Clamp and Transvaginal Doppler Probe detect blood flow of blood vessels using an 8 MHz pulsed-wave Doppler sensor. The Doppler crystals in all three devices are located at the distal end to allow for forward detection of blood flow.

The Cstat and the predicate VCS-A Clamp are intended to temporarily occlude blood vessels. The Transvaginal Doppler Probe is not intended to occlude blood vessels.

The Cstat and the predicate Medical Designs Hand Drill are each constructed of glass-filled nylon.

7. Brief summary of nonclinical tests and results:

The Cstat 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 Cstat does not raise new issues of safety, effectiveness, or performance.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Vascular Control Systems, Inc.
c/o Ms. Kathleen Roberts
Senior Regulatory Affairs Specialist
32236 Paseo Adelanto, Suite E
San Juan Capistrano, CA 92675

Re: K032125
CSTAT Vascular Clamp
Regulation Number: 21 CFR 870.4450, 892.1570
Regulation Name: Vascular Clamp and Transducer, Ultrasound, Diagnostic for
Regulatory Class: Class II (two)
Product Code: DXC, ITX
Dated: November 10, 2003
Received: November 12 2003

Dear Ms. Roberts:

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 Technology, Inc. Doppler Transceiver, 8 MHz Selectable Channel, and Part number 108900, as described in your premarket notification:

Transducer Model Numbers

09-0014-01
09-0014-02

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 post-clearance 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>".

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If you have any questions regarding the content of this letter, please contact CDR O.D. Hottenstein, Ph.D. at (301) 443-8262, extension 163.

Sincerely yours,

Donna R. Lochner

[Signature] Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K032125

Device Name: Cstat

Indications for Use: The Cstat is intended for detection and temporary occlusion of blood vessels during vascular surgical procedures.

Prescription Use X
(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
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana D. Cochran
(Division Sign-Off)
Division of Cardiovascular Devices

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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) Vascular				N						
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
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 # 09-0014-01, 09-0014-02

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)

Diana R. Kochner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032125