SEP 16 1999

K990642

EchoCath Inc.
510(k) Submission
EchoFlow Doppler Blood Velocity Meter
510(k) Summary

(1) Submitters name, address, telephone number, contact person, and date of preparation

Name: EchoCath Inc.
Address: PO Box 7224
Princeton, NJ 08543
Telephone Number: 609-987-8400
Contact person:

Dr. George H. Myers
Medsys Inc
377 Route 17
Hasbrouck Heights NJ 07604

201-727-1703 fax: 201-727-1708

Date of preparation: September 2, 1999

(2) Names

Trade name: EchoFlow Doppler Blood Velocity Meter BVM-1
Common Name: Doppler ultrasonic blood-flow measuring system
Classification Name: Flowmeter, blood, ultrasonic, w/wo calibration, and Transducer, Ultrasonic

(3) Predicate devices:

1. Ultramed Ultraplex, K861378
2. Zertl K921377, P/Meter

(4) Description

The EchoFlow velocity system is a computer-based ultrasonic Doppler blood velocity measuring system used to measure blood velocity in vessels beneath the skin. It can either be used for measurement on the surface of the skin, or for intraoperative measurements. A 10 MHz CW probe is used. When used intraoperatively, a sterile sheath covers the probe and 6 feet of cable coming from the probe.

A unique feature of the system is that the angle between the probe and the axis of the blood vessel does not have to be known. An accuracy of 15% is maintained if this

angle changes by as much as $\pm 15^{\circ}$. This is done by using a unique probe that emits two beams at known angles with respect to each other, as explained in a later section. Thus, the system is well-adapted to measuring flow in blood vessels beneath the surface of the skin, where the exact angle of the axis of the blood vessel cannot be determined. The unit can detect large blood vessels at depths up to 12 mm and small blood vessels at depths up to 10 mm in normal tissue. It will not detect any signals at depths greater than 15.5 mm from the probe tip.

(5) Intended Use

The EchoFlow BVM-1 is an ultrasonic Doppler system that can be used to measure blood flow velocities in blood vessels. It can be used either for measurement of vessels below the skin, or for intraoperative measurements. It is not intended for cardiac or fetal use. A 10 MHz probe is supplied. The unit maintains its specified accuracy even if the angle between the probe face and vessel axis is as much as $\pm 15^{\circ}$, unlike conventional Doppler systems where the angle between the flow direction and the probe must be accurately known. The unit can detect large blood vessels at depths up to 12 mm and small blood vessels at depths up to 10 mm in normal tissue. The system will not detect any signals from vessels more than 15.5 mm from the probe.

(6) Comparison to Predicate Devices

(a) The EchoFlow system has the same intended use, method of application, and clinical utility as the predicate devices. It differs from them in that it has a special transducer (the "diffractive transducer") which makes it unnecessary to know the angle between the direction of blood flow and the plane of the transducer.

(b) Performance data

(1) Non-clinical tests:

Electrical Safety
Doppler accuracy
Software validation
Depth penetration
Ultrasonic emissions tests

(2) Clinical test

Clinical validation of the operation of the system in animals and a human.

(3) Conclusions

The conclusions drawn from the non-clinical tests and clinical tests demonstrate that the device is as safe and effective, and performs as well or better than the legally marketed device identified in paragraph 3.

EchoCath Inc.
K990642
EchoFlow
Revised Intended Use Statement
September 2, 1999

Diagnostic Ultrasound Indications for Use Form

Page 1 of 2

510(k) Number: K990642

Device Name: EchoFlow Doppler Blood Velocity Meter BVM-1

Indications For Use:

The EchoFlow BVM-1 is an ultrasonic Doppler system that can be used to measure blood flow velocities. It can be used either for measurement of vessels below the skin, or for intraoperative measurements. It is not intended for cardiac or fetal use. A 10 MHz probe is supplied. The unit maintains its specified accuracy even if the angle between the probe face and vessel axis is as much as ±15°, unlike conventional Doppler systems where the angle between the flow direction and the probe must be accurately known. The unit can detect large blood vessels at depths up to 12 mm and small blood vessels at depths up to 10 mm in normal tissue. The system will not detect any signals from vessels more than 15.5 mm from the probe.

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)					N					
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

(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) X

Diagnostic Ultrasound Indications for Use Form

510(k) Number: K990642

Device Name: IOP10 Transducer for EchoFlow Doppler Blood Velocity Meter BVM-1

Indications For Use:

The IOP10 transducer for the EchoFlow BVM-1 is intended to be used with that unit to measure blood flow velocities. It can be used either for measurement of vessels below the skin, or for intraoperative measurements. It is not intended for cardiac or fetal use. A 10 MHz probe is supplied. The unit maintains its specified accuracy even if the angle between the probe face and vessel axis is as much as $\pm 15^{\circ}$, unlike conventional Doppler systems where the angle between the flow direction and the probe must be accurately known. The unit can detect large blood vessels at depths up to 12 mm and small blood vessels at depths up to 10 mm in normal tissue. The system will not detect any signals from vessels more than 15.5 mm from the probe.

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)					N					
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) X

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 1999

David Vilkomerson, Ph.D.
Executive Vice President
EchoCath, Inc.
P.O. Box 7224
Princeton, NJ 08543-7224

Re: K990642
EchoFlow™ Doppler Blood Velocity Meter
Regulatory Class: II (two)
Product Code: 74CAS and 74JOP
Dated: February 23, 1999
Received: July 2, 1999

Dear Dr. Vilkomerson:

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) 594-4648. 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

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

Enclosure

510(k) Number (if known): K990642

Diagnostic Ultrasound Indications for Use Form

Device Name: EchoFlow Doppler Blood Velocity Meter BVM-1

Indications for Use:

The EchoFlow BVM-1 is an ultrasonic Doppler system that can be used to measure blood flow velocities. It can be used either for measurement of vessels below the skin, or for intraoperative measurements. It is not intended for cardiac or fetal use. A 10 MHz probe is supplied. The unit maintains its specified accuracy even if the angle between the probe face and vessel axis is as much as $\pm 15^{\circ}$, unlike conventional Doppler systems where the angle between the flow direction and the probe must be accurately known. The unit can detect large blood vessels at depths up to 12 mm and small blood vessels at depths up to 10 mm in normal tissue. The system will not detect any signals from vessels more than 15.5 mm from the probe.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number k 990642