DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 1997

David Lerner
Sr. Engineer
BioMedix, Inc.
P.O. Box 1419
Camden, NJ 08105

Re: K973644
FLOSTAT VASCULAR LAB
(Doppler Ultrasound/Plethysmograph)
Dated: September 11, 1997
Received: September 24, 1997
Regulatory Class: II
21 CFR 892.1540/Procode: 90 JAF

Dear Mr. Lerner:

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 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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the FLOSTAT VASCULAR LAB, as described in your premarket notification:

Transducer Model Number

8.0 MHz Peripheral Vascular
5.0 MHz Peripheral Vascular
8.0 MHz Ophthalmic Periorbital

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 Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), 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 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 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 Paul Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page____of____

510(k) Number (if known): K973644

Device Name: FloSTAT Vascular Lab

Indications For Use: See Attached

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Bryan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973644

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over-The-Counter Use____

(Optional Format 1-2-96)

# Intended Use

The BioMedix, Inc. Flostat Vascular Lab is a device for the use in the diagnosis of the etiology and extent of vascular pathology primarily in the peripheral vasculature and, in a more restricted sense, in the central vasculature(periorbital region ONLY). These tasks are accomplished via three separate modalities, each of which can be use to test either the arterial or venous system. The three modalities are 1) Pneumoplethysmography (blood pressure cuff air inflation), 2) Photoplethysmography (change in infrared light reflectance on skin as a relection of larger branches) and 3) Simple continuous wave doppler ultrasound velocity waveform measurement. NONE of these testing modalities are intended for FETAL USE and the devices and instruction manuals are so labelled.

The air pump Pneumoplethysmograph and infrared Photoplethysmograph are for use in studying the PERIPHERAL VASCULATURE ONLY.

The 5 MHz. continuous wave doppler ultrasound velocity meter and the 8 MHz. continuous wave doppler ultrasound velocity meter are for use in studying the PERIPHERAL VASCULATURE ONLY.

There is a separate control setting labelled clearly on the FLOSTAT VASCULAR LAB - 'Ophthalmic-8 MHz.' doppler which is intended for periorbital doppler studies ONLY. The 'Ophthalmic-8 MHz.' mode is an 8 MHz. continuous wave doppler ultrasound velocity meter exactly the same as the 8 MHz. continuous wave doppler velocity meter except that the 'Ophthalmic-8 MHz.' doppler has substantially lower acoustic output which conforms to the safety standards for periorbital studies specified by the Food and Drug Administration (FDA). Through medical studies performed by the scientists at the FDA, it has been determined that ultrasound acoustic levels as rated by various figures of merit (eg. ISPTA, etc.) are safe for different areas of the body.

For this reason, DO NOT EVER PERFORM PERIORBITAL STUDIES WITH THE DOPPLER IN ANY MODE OTHER THAN THE 'Ophthalmic-8 MHz.' MODE. Labels will also be placed on the doppler transducer that they are NOT FOR FETAL USE and specifying the correct frequency(5 MHz or 8 MHz).

The doppler section is intended to generate velocity waveforms and values for study and audio output for physician analysis of the arterial and venous system.

The Ultrasonic Doppler device at 5 MHz. and 8 MHz. applies ultrasound energy through the extremities of the subject to assess blood velocity, blood velocity waveform morphology, spectrum analysis, pressure, and patency of PERIPHERAL VESSELS.

The Ultrasonic Ophthalmic- 8 MHz. device applies ultrasound energy to the periorbital region to assess blood velocity, blood velocity waveform morphology, and spectrum analysis in this area.

The Pneumoplethysmograph is used to gauge the arterial system through volume pulse recording studies and is used to gauge the venous system through maximum venous outflow studies.

The Photoplethysmograph is used to gauge the arterial system through pulse waveform analysis and is used to gauge the venous system through venous reflux time tests. Full clinical information is provided in the Operators Instruction Manual(enclosed herein).