DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 1997

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

Re: K973857
Flostat Vascular Report Generator (VRG)
Dated: September 22, 1997
Received: October 9, 1997
Regulatory Class: II
21 CFR 892.1540/Procode 90 JAF

Dear Mr. Lerner:

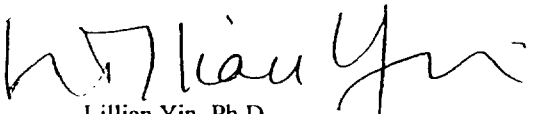
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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 requirement, 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) 594-4613. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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

510(k) Number (if known): K973857

Device Name: FLOSTAT VASCULAR REPORT GENERATOR

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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973857

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Intended Use

The BioMedix, Inc. Flostat Vascular Report Generator is a device for the use to display the outputs from three strip chart recorder based peripheral vascular diagnostic instruments on a PC printer. In essence, this is changing one printer for another. This generic device can bu used to input a signal from any device into a computer but is intended soley for use in conjunction with peripheral diagnostic instruments. Blood pressures, displayed digitally, may be recorded with the original cuffs provided by the original manufacturer. No change in equipment or technique is warranted.

The three target devices are the Imex Corp. 3000 Series, 301 Series, and The Life Sciences Corp./HealthWatch PVR Series diagnostic devices. All these incorporate analog or digital pen strip chart recorders to display the output waveforms. The sole use of the VRG is to display the waveforms on the PC printer. The lowest resolution dot matrix printer with 90x90 dots per inch(and certainly much higher resolution laser printers) has a much higher resolution than the relatively meager 100 Hz bandwidth that an analog pen recorder can provide. No alterations in the clinical instructions, indications, methodologies, or outcomes will occur. The VRG is simply connected to an analog output path on the target device. The VRG is then connected(via a high ESD rated RS-232 driver) to the computer. The waveforms are brought into the computer and the opportunity is provided for printing to a printer. The intended use of the VRG-Vascular Diagnostic Unit tandem is the same as the original intended use of the original vascular diagnostic unit(ie. peripheral vascular studies).

The BMX Vascular Report Generator passes the output information of a peripheral vascular deviceto a computer and then onto a printer. All outputs of a peripheral vascular device, throuhg the VRG, can displayed, including data that can be shown as a spectrum analysis. The Vascular Report Generator does not change the output of a peripheral vascular devicebut only allows the computer to display the informa- in various forms.