



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR - 4 1998

Mr. Darren D. Dershem  
Biosensor Corporation  
7001 East Fish Lake Road  
Maple Grove, MN 55311-2833

Re: K974192  
Biosensor Holter Monitor System  
Regulatory Class: II (two)  
Product Code: 74 DQK  
Dated: February 12, 1998  
Received: February 17, 1998

Dear Mr. Dershem:

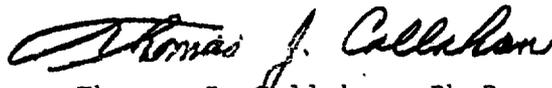
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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" (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,



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): K974192

Device Name: BIOSENSOR HOLTER MONITOR SYSTEM

**Indications For Use:**

The Biosensor Frequency Domain Heart Rate Variability , (FD HRV), analysis option is being incorporated into the Biosensor Holter Monitor System for quantification and graphical displays of heart rate changes over a specific monitoring period as an aid to other clinical diagnostic techniques.

The FD HRV graph is modeled after the recommendations of the Task Force of the European Society of Cardiology (Circulation. 1996;93: 1042-1065). FD HRV is intended to provide HRV spectra for any selected time segment of 5 minutes of duration or longer, at the physician's discretion.

**Precaution:**

Computerized ECG analysis should not replace diagnosis by a qualified physician. The physician should verify that the reported data is accurate before applying clinical conclusions.

Since various neural, respiratory, and endocrine factors are known to affect heart rate variability, the significance of the data must be determined by a physician.

FD HRV analysis may differ among devices from different manufacturers since methods and algorithms may vary. Caution should be used in applying conclusions drawn from studies with other devices.

Validation data for FD HRV will be made available upon request.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*CC*

Prescription Use    
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use