



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

MAR - 4 1998

Mr. Steve Springrose
Biosensor Corporation
7001 East Fish Lake Road
Maple Grove, Minnesota 55311-2833

Re: K974546
Trade Name: Biosensor Holter Monitor System with QT Interval
Regulatory Class: II
Product Code: 74 DQK
Dated: October 27, 1997
Received: December 4, 1997

Dear Mr. Springrose:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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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,

A handwritten signature in black ink, reading "Thomas J. Callahan". The signature is fluid and cursive, with the first name "Thomas" being the most prominent part.

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

Enclosure

Intended Use

Caution: Federal law restricts this device to sale by or on the order of a physician.

The Biosensor Holter Monitor System is intended for patients requiring ambulatory (Holter) monitoring from 1 to 24 hours. Such monitoring is most frequently used for the indications below. (Portions from Ambulatory Electrocardiograph Recording, Wegner NK, Mock MB, and Reingquist I, Year Book Medical Publishers, 1981.)

1. Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
2. Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.
3. Evaluation of patients for ST segment changes.
4. Evaluation of patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery.)
5. Evaluation of clinical syndromes or situations where arrhythmia may increase the risk of sudden death.
6. Clinical and epidemiological research studies.

Prescription Use _____
(Per 21 CFR 801.109)

[Signature]
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K974546

K974546