

JUN 14 1999

Section 2 - Safety and Effectiveness Summary and Certifications

Safety

For safe use of Holter systems, labeling and documentation must be complete. Standards for these are also covered in ANSI/AAMI EC11-1982.

Effectiveness

Holter analysis systems contain software, which must perform effectively, accurately, and reliably. Recommended standards and test methods for the performance of these systems are also compiled in detail in the Association for the Advancement of Medical Instrumentation draft standard for Holter systems.

In addition to these, because of lack of proper user training, problems may arise regarding the following:

- (a) Lead placement (Correct positions for electrodes are explained in ECG textbooks such as "Harrison's Principles of Internal Medicine", Eds. R.G. Petersdorf, R.D. Adams, E. Braunwald, K.J. Isselbacher, J.B. Martin and J.D. Wilson, 10th edition, pp: 1320-21. McGraw Hill, 1983).
- (b) Line Interference (A comprehensive reference list for causes and reduction methods for line interference is given in "A new technique for line interference monitoring and reduction in biopotential amplifiers", Y.Z. Ider and H. Koymen, IEEE Trans. Biomedical Engineering, Vol. 37, pp. 624-31, 1990.) Patient recorder hardware with 05-40 Hz bandpass filters can reduce partially or substantially an problems with line interference.
- (c) EMG (myopotential) interference (A low pass filter may be provided as an option as too much muscle interference may be encountered during an Holter recording. Users should be notified continuously when this filter is in use, since low pass filters may affect the diagnostic value of the ECG recording information. The CMS Holter Analysis System provides such notification on screen.)
- (d) Baseline wander (High pass correction filters may be provided as an option as baseline wander may occur during Holter recording. Users should be notified continuously when this filter is used, since baseline wander filters may affect the diagnostic value of the recording. The CMS Holter Analysis System provides such notification on screen.)
- (e) Averaging (In Holter systems, ST level changes must be accurately measured for each lead). Due to myopotential, baseline wander and other noise interference, such measurements cannot be reliably made using a single beat. Therefore, beats are averaged and measurements are made from average beats to minimize errors.

(f) Diagnostic Accuracy (In Holter systems that measure heart rate, arrhythmia content, ST values and other ECG parameters, the algorithms used to make such measurements and report trends to the physician influence the quality of information provided to the physician. Testing of the diagnostic accuracy of the ST measurements, QRS detector and VE detector are necessary to evaluate the value of the measurements and trends supplied to the physician for review.



JUN 14 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Steve Springrose
Vice President
Biosensor Corporation
11481 Rupp Drive
Burnsville, MN 55337

Re: K990956
Biosensor Holter Monitor System Software, Model 1005
Regulatory Class: II (two)
Product Code: DQK
Dated: March 17, 1999
Received: March 22, 1999

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 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 (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" (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, 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): K990956

Device Name: Ambulatory (Holter) ECG

Indications For Use:

Ambulatory (Holter) ECG intended use:

The Biosensor CMS Holter Analysis system is intended for patients requiring ambulatory (Holter) monitoring from 1 to 48 hours. Such monitoring is most frequently used for the indications below.

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 a patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery.)
5. Clinical and epidemiological research studies.
6. Evaluation of patients with pacemakers
7. Reporting of time and frequency domain heart rate variability
8. Reporting of QT Interval.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

[Signature]

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K990956

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)