NOV 24 1999

K993617

Section 2: 510(k) SUMMARY

- **Substantially Equivalent (SE) To:** Biosensor Model #1005
  510(k) # K950944

Modification Background

The essence of this modification is a change of the digital Holter recorder hardware to a smaller configuration with reduced power consumption and the removal of ECG analysis capabilities from the device. In connection with this modification, the methodology of the pacemaker detection logic has been modified slightly, and its performance validated as reported herein. As a result of this modification, ECG analysis is not a part of this device, but rather is performed by software installed in the Holter Analyzer which is subject to independent 510(k) review, as in the Company's earlier filing (K990956).

The above changes do not affect the intended use of the device or alter the fundamental scientific technology of the device, as is demonstrated on the following pages.

- **Comparison To The SE Device:**

Attribute	**DigiTrakPlus**	**Model #1005**
Storage capacity	Up to 48 hours	24 hours
Memory type	Flash (non-volatile)	Flash (non-volatile)
Memory portability	Non-removable	Non-removable
On-board ECG analysis	No	Yes
Liquid Crystal Display (LCD)	Yes	No
Data transfer method	USB port	Bi-directional parallel I/O
Pacemaker detection & reporting	Yes	Yes
Belt clip	Yes	No
Battery	One AA	Four AA
Size	8.5 x 6.5 x 2 cm	15 x 6 x 2 cm
Weight	100 g	140 g

NOTE: Together with this Special 510(k), another Special 510(k) has been filed on a similar device (DXP1000) utilizing alternative hardware which is slightly larger in size. Both devices incorporate the same fundamental scientific technology, and indeed a substantially identical electro-mechanical design. For clarity, the submitter wishes to note to the reviewer that these two devices are essentially the same other than the size and weight characteristics noted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1999

Mr. David Norberg
Regulatory Affairs Representative
Braemar, Inc.
11481 Rupp Drive
Burnsville, Minnesota 55337

Re: K993617
DigiTrakPlus Holter Recorder
Regulatory Class: II (two)
Product Code: MWJ
Dated: October 25, 1999
Received: October 26, 1999

Dear Mr. Norberg:

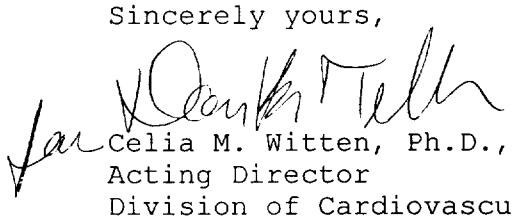
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,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



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DigiTrakPlus Holter Recorder

510(k) Number: K993617

Indications for Use:

(No change from predicate device)

The electrocardiogram (ECG) is a graphic description of the electrical activity of the heart. This activity is recorded from the body surface by a group of electrodes positioned at predefined places to reflect the activity from different perspectives. Depending on how these electrodes are placed, the ECG waveforms are considered as separate linearly dependent signals. Presently, the ECG is the most prominent and widely used non-invasive cardiac diagnostic technique. There exists a significant accumulation of correlated clinical data which provides a powerful basis for evaluation of these biophysical signals. Twenty-four or forty-eight hour ECG recordings can be of great value in patient assessment.

Ambulatory (Holter) ECG intended use:

The DigiTrakPlus Holter recorder 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

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K993617