DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 20 1998

Richard A. Bonato, Ph.D.
Vice President
Braebon Medical Corporation
63 Acklam Terrace
P.O. Box 72094
Kanata, Ontario K2K 2P4
Canada

Re: K981969
Trade Name: Ultima Body Position Sensor
Regulatory Class: Unclassified
Product Code: LEL
Dated: May 28, 1998
Received: June 4, 1998

Dear Dr. Bonato:

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) 594-4595. 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K981969

Device Name: *Ultima* Body Position Sensor™

Indications For Use:

The BRAEBON MEDICAL CORPORATION *Ultima* Body Position Sensor™ is intended for use during sleep disorder studies as an indicator of body position. The sensor uses a three-volt lithium battery and plugs directly into either a DC amplifier or multiplexer.

The target population of the *Ultima* Body Position Sensor is all children and adult patients who are screened during sleep disorder studies. The majority of the screenings occur at a sleep laboratory although the sensor can also be used in home studies.

The *Ultima* Body Position Sensor is intended for use only by or on the order of a physician. The *Ultima* Body Position Sensor is similar in design, function and intent as the legally marketed Sleep Position Indicator, Model BPI1, k940013; Mini-Tracker, k923033.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Russell Fyne for JZP

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981969

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

(Optional Format 1-2-96)