BRAEBON
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K984431

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DEC 30 1998

# SUMMARY AND CERTIFICATION

## 510(K) SUMMARY

## SAFETY AND EFFECTIVENESS SUMMARY

Safety and effectiveness information concerning this airflow sensor is summarized below.

Because this is not a class III device, the special certification defined for this section is not required.

**Prepared by:** BRAEBON Medical Corporation
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**Telephone:** (613) 591-8990

**Contact Person:** Richard A. Bonato, Ph.D.

**Date on which this summary was prepared:** December 4, 1998

**Common name:** Airflow Pressure Sensor

**Classification name:** Breathing frequency monitor (per CFR 868.1860)

**Predicate device:** *Ultima* Airflow Sensor, Braebon Medical Corporation, k981445

**Description of the Device:**

The *Ultima* Airflow Pressure Sensors, Models #0580H and #0580L, are small interface devices which convert levels of air pressure to corresponding levels of voltage which can be recorded on any FDA-cleared physiological recorder intended to record low-level electrical signals. The purpose of the device is to detect respiratory airflow. There is one pneumatic input for air pressure, and one set of electrical outputs representing the electrical equivalent of the pressure. The electrical outputs are the active or positive output and the reference or negative output.

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This device uses a disposable nasal cannula with a disposable 0.2 µm hydrophobic filter. The cannula and filter attach to the patient and connect to the pressure input labeled "INPUT" using a standard luer connector. The electrical output connectors are made with 1.5 mm-safety connectors that connect to either an FDA-cleared AC amplifier or an FDA-cleared DC amplifier with a low frequency filter setting of less than 0.05 Hz and a high frequency filter setting of 15 - 30 Hz.

The *Ultima* Airflow Pressure Sensor consists of a red ABS plastic enclosure measuring approximately 1.5"(W) x 2.8"(L) x 0.6"(H). The device is battery powered with one 3.6 volt 1/2AA lithium cell. The estimated battery life is 450 hours (50 – eight hour uses), with an On/Off switch provided to conserve battery life when not in use. The device has a 0.14-Hz blinking status LED: green indicates proper operation, red indicates low battery. The battery can be replaced by removing the battery cover, removing the battery and inserting a new one in the orientation shown in the battery compartment of the unit. The pressure sensor is attached either to a bed frame or to a wall with a Velcro strap.

**Intended Use:**

The *Ultima* Airflow Pressure Sensor™ is intended for use during sleep disorder studies as a qualitative measure of respiratory airflow for recording onto an FDA-cleared data acquisition system. Respiratory pressures are converted into voltage signals for input to a physiological recorder. The sensor uses a 3.6-volt lithium battery and plugs directly into the patient headbox or to an FDA-cleared DC amplifier. A disposable nasal cannula with a 0.2-micron hydrophobic filter attaches to the patient and connects to the input of the *Ultima* Airflow Pressure Sensor.

**Patient Population:**

The target population of the *Ultima* Airflow Pressure 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.

**Safety and Effectiveness:**

The maximum voltage within the *Ultima* Airflow Pressure Sensor is 3.0 volts DC, based on the use of one 3.6 volt ½AA lithium battery. There is no direct electrical connection to the patient because a seven-foot non-conductive oxygen cannula attaches to the patient and connects to the pressure sensor. The sensor is plugged into an isolated FDA-cleared amplifier/recording system: no direct electrical contact is ever made with the patient. All circuitry is enclosed in a non-conductive ABS enclosure using a hex screw such that the patient can not accidentally remove

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the battery. Due to these low voltages, there is no risk of electrical shock to either the patient or health-care provider.

Laboratory testing has been performed using this device in place of the predicate device for respiratory airflow monitoring. These tests conclude that the electrical signals recorded using the *Ultima* Airflow Pressure Sensor provide equivalent informational content to the signals recorded using the predicate device.

The following comparison is provided as a summary of technological characteristics relative to the predicate device. This table demonstrates that the *Ultima* Airflow Pressure Sensor has no significant differences from the predicate device that would adversely affect product safety and effectiveness.

| | |
|---|---|
| Intended Use | No difference |
| Indication Statements | No difference |
| Population | No difference |
| Number of Input Channels | No difference. Both the subject and predicate devices have one input channel. |
| Number of Output Channels | No difference. Both the subject and predicate devices output one channel. |
| Electrical Output Connectors | No difference. Both the subject and predicate devices use 1.5-mm safety connectors. |
| Method of Connection to Patient | No significant difference. Both the subject and predicate devices are cannula style. The subject device uses a plastic tubing and cannula set for patient connection. There are no wires or other metal parts connected to the patient. The sensor assembly of the predicate device also attaches to the patient in a manner similar to a cannula. |
| Composition of Plastic Battery Enclosure | No difference. Both the subject and predicate devices are made of red ABS plastic. |
| Power Source | No significant difference. Both the subject and predicate devices use replaceable lithium batteries |

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| | |
|---|---|
| | only. |
| Safety Characteristics | No significant difference. Both the subject and predicate devices provide for patient isolation because there is no direct connection of wires to the patient in either case. The subject device uses plastic tubing; the predicate device uses an insulated thermistor assembly. Both the subject and predicate devices connect to FDA cleared recorders using approved safety connectors. |
| Re-use Restrictions | Subject device is for single-use only. Predicate device requires disinfection and cleaning procedures for re-use. |
| Sensor Technology | The subject device uses a solid-state pressure transducer, which converts small changes in air pressure into small voltage changes. The predicate device uses an electrical thermistor, which converts small resistance changes caused by the airflow into small voltage changes. |
| Performance data conclusions | No difference. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 30 1998

Richard A. Bonato, Ph.D.
Braebon Medical Corporation
P.O. Box 72094
Kanata, ON, K2K 2P4
CANADA

Re: K984431
*Ultima* Airflow Pressure Sensor, 0580H and 0580L
Regulatory Class: II (Two)
Product Code: 73 BZQ
Dated: December 18, 1998
Received: December 22, 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 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" (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/dsma/dsmamain.html."

Sincerely yours,

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

## Indications for Use Statement

**510 (k) Number** K984431 (To be assigned)

| | |
|---|---|
| **Device Name:** | *Ultima* Airflow Pressure Sensor, 0580H and 0580L |
| **Indications for Use:** | An indicator of respiratory airflow for recording onto a data acquisition system. |
| **Target Population:** | Children and adult patients who are screened during sleep disorder studies |
| **Environment of Use:** | The majority of screenings occur at a sleep laboratory. |

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Mark Kramer

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

510(k) Number _____

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