BRAEBON
MEDICAL
CORPORATION

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Ogdensburg, NY
13669-3474

1-120 Walgreen Drive
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Ontario, Canada
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K061764

SEP - 6 2006

510(K) Summary

BRAEBON Medical Corporation MediByte™

August 23, 2006

The following safety and effectiveness summary has been prepared according to the requirement for 510(k) summaries specified in 21 CFR 807.92c.

1.0 Manufacturer Name

BRAEBON Medical Corporation
Suite 1, 120 Walgreen Drive RR#3
Carp, Ontario
Canada, K0A 1L0

2.0 Proprietary Name of Device

MediByte™

3.0 Common Name of Device

Polysomnograph / Portable Sleep Data Recorder

4.0 Device Classification

Devices of this type have been classified as class II by the Anesthesiology Devices Panel. Devices of this classification have a classification code of MNR, Ventilatory Effort Recorder (21 CFR 868.2375).

5.0 Intended Use

The MediByte™ is a portable sleep data recorder used to record physiological signals during sleep while the patient is either at home or in a clinical environment. The data is downloaded after the recording is completed and the assist software enables the trained human professional – typically a Registered Sleep Technologist or Medical Doctor - to verify the results of the study and generate a report.

Target Population: Children and adult patients who are screened during sleep disorder studies.

Environment of Use: The majority of the screenings occur either in the home at in a clinical setting.

The MediByte™ is intended to be used only by or on the order of a physician.

6.0 Device Description

The MediByte™ is a palm-sized recording device capable of acquiring and storing physiological signals from FDA-cleared sensors and transmitting the physiological data to a computer through the Universal Serial Bus (USB) port.

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The MediByte™ records up to 8 channels of physiological signals: either electromyogram (EMG), or electrocardiogram (EKG); as well as chest effort; abdominal effort; airflow pressure; snoring; body position; arterial oxygen saturation (SpO_2); and pulse rate. The signals cannot be viewed in real time, but can be downloaded after collection for assisted analysis by a human professional trained in the analysis and reporting of sleep disorders medicine.

The MediByte™ is powered by one ½ AA battery and connects to a computer via the MediByte™ USB communication cable. The MediByte™ and sensors are both typically worn by the patient during the recording and all patient contact materials consist of latex-free biocompatible material.

7.0 Predicate Device Equivalence

We are claiming substantial equivalence to the following devices all manufactured and sold by BRAEBON Medical Corporation:

1. MediPalm®; K031202, Braebon Medical Corporation
2. Ultima Airflow Pressure Sensor; K984431, BRAEBON Medical Corporation
3. Ultima Respiratory Effort Sensor; K982216, Braebon Medical Corporation
4. Ultima Snore Microphone; K020312, Braebon Medical Corporation

8.0 Similarities and Differences Between Subject and Predicate Devices

Intended Use	No difference
Indications Statement	No difference
Method of Connection to Patient	No difference
Power Source	No difference. The MediByte™, like the predicate devices, is battery powered.
Safety Characteristics	No difference.
Reuse and Hygiene Characteristics	No difference.
Design	No difference. The MediByte™ is smaller than the Medi*Palm*® predicate device.
Performance Data Conclusions	No difference.

9.0 Performance Testing

Functional testing was performed to confirm that the MediByte™ is capable of meeting its stated performance specifications and that the device output is readable. MediByte™ passed all tests.

All software testing was performed in accordance with the May 2005 "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" published by the Office of Device Evaluation. The MediByte™ passed all tests.

All software verification and validation testing was performed in accordance with the January 11, 2002 "General Principles of Software Validation; Final Guidance for Industry and FDA Staff." The MediByte™ passed all tests.

All environmental and electrical safety testing was performed in accordance with the November 03, 1997 "Electroencephalograph Devices Guidance for 510(k) Content." The MediByte™ passed all tests.

Analysis of overnight studies supports a substantial equivalence determination. The MediByte™ was run to verify that readable, appropriate signals were being recorded. Simulation tests comparing the MediByte™ to the

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MediPalm® were also performed to gather comparative performance data. The performance of the BRAEBON Medical Corporation MediByte™ (subject device) was identical to that of MediPalm® (predicate device).

10.0 Conclusions

We conclude that MediByte™ is equivalent in safety and performance to the legally marketed predicate devices. The MediByte™ meets its stated performance specifications and the criteria outlined in the Reviewers Guidance publication specified above, and the MediByte™ will operate safely in the intended environment and fulfill its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Richard A. Bonato, Ph.D.
Braebon Medical Corporation
120 Walgreen Drive,
Suite 1, RR#3
Carp, Ontario
CANADA KOA 1L0

SEP -6 2006

Re: K061764
Trade/Device Name: MediByte™
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR, DQA
Dated: August 23, 2006
Received: August 25, 2006

Dear Dr. Bonato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

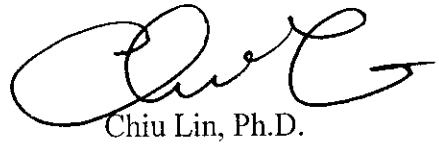
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K061764**

Device Name: MediByte™

Indications for Use: The MediByte™ is a portable sleep data recorder used to record physiological signals during sleep while the patient is either at home or in a clinical environment. The data is downloaded after the recording is completed and the auto assist software enables the trained human professional – typically a Registered Sleep Technologist or Medical Doctor - to verify the results of the study and generate a report.

Target Population: Children and adult patients who are screened during sleep disorder studies.

Environment of Use The majority of the screenings occur either in the home at in a clinical setting.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

...ion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ection Control, Dental Devices
...) Number: K061764