AUG 2 9 2003

SECTOR Medical Corp

320 Northpoint Parkway
Suite P
Acworth, Georgia 30102

Phone: 770.975.1384
Fax: 770.975.1385

# 510(k) SUMMARY

**The assigned 510(k) number is:** K030379

**Prepared By:** Sector Medical Corp.
320 Northpoint Parkway, Suite P
Acworth, GA 30102

**Telephone:** 770.975.1384
**Fax:** 770.975.1385

**Contact:** Bradley Jeffries, MD, MS

**Date prepared:** August 28, 2003

**Proprietary name:** ApLab™
**Classification name:** Ventilatory Effort Recorder
**Common name:** Airflow Pressure Sensor

**Classification:** Class II
**Regulation number:** 868.2375
**Product code:** MNR

**Predicate device(s):** SensorMedics SomnoStar α Series Sleep System
510(k) Number: K012085

Biomec SleepFlow
510(k) Number: K020607

**Description of device:**

The ApLab is a re-usable, respiratory pressure sensor system intended to provide a recording of respiratory pressure during sleep. This physician prescribed device will provide a screening index for and aid in the diagnosis of obstructive sleep apnea syndrome. The device is about the size of a common beeper that contains proprietary electronic circuitry and embedded software. The ApLab utilizes a disposable, lightweight plastic nasal cannula that can be conveniently worn while sleeping at home. At completion of a sleep study the device is returned for data analysis and report generation.

**Intended use:**

ApLab is intended for use in recording respiratory nasal pressure during sleep. The device is intended for use as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's score.

**Technological Characteristics:**

The comparison table is provided as a summary of the technological characteristics relative to the predicate devices. This is to demonstrate that ApLab has no significant differences from the predicate device that would adversely affect product safety and effectiveness.

| Comparison Parameter | SensorMedics SomnoStar α Series Sleep System K012085 | Biomec SleepFlow K020607 | Sector Medical Corp ApLab |
|---|---|---|---|
| Intended Use | Recording physiological parameters during sleep, including respiratory flow and effort, EEG, electroculogram, electromyogram, ECG, oxygen saturation, etc. | Recording airflow, snore, body position, thoracic effort, abdominal effort and body position during sleep. | Recording respiratory nasal pressure during sleep. |
| Population | Not specified | 2 yrs or older | 2 yrs or older |
| Power Source | 115 VAC | 3-Volt (2AA in series) | 3-Volt Lithium battery |
| Number of Channels | Variable with a nominal channel count of 14 | Four channels | Single channel |
| Method of Connection to the Patient | Plastic tubing and cannula for pressure sensing; elastic cloth material for effort belts; insulated electrical sensors. | Plastic tubing and cannula for pressure sensing; elastic cloth material for effort belts | Plastic tubing and cannula for pressure sensing; elastic cloth material belt to support unit. |
| Safety Characteristics | Uses non-conducting, disposable, plastic cannula containing a hydrophobic 0.2 micron filter; insulated electrical connections to ensure patient isolation. | Use non-conducting, disposable, plastic cannula containing a hydrophobic 0.2 micron filter. | Use non-conducting, disposable, plastic cannula containing a hydrophobic 0.2 micron filter. |
| Re-use | Plastic cannula & filter are single use disposable. Remaining portions require cleaning. | Plastic cannula & filter are single use disposable. Remaining portions require cleaning. | Plastic cannula & filter are single use disposable. Remaining portions require cleaning. |
| Sensor Technology | Utilizes various sensor technologies including solid-state pressure sensor, Gold cup electrodes, thermistors, strain gauges, and oximetry. | Utilizes solid-state pressure sensor that converts pressure changes to electrical signal levels. | Utilizes solid-state pressure sensor that converts pressure changes to electrical signal levels. |

**Performance Data:**

**Clinical tests:**

In Clinical tests, ApLab automatic scoring and SomnnoStar α autoscore PSG were compared to a manually scored SomnoStar α PSG. Breath by breath accuracy was verified manually on both systems.

The efficacy results are:

- The ApLab and PSG were equivalent in mean AHI.
- The ApLab sensitivity was 69% with a PPV of 65% on an apnea and hypopnea event count when compared to a manually scored PSG.
- The autoscored PSG sensitivity was 21% with a PPV of 58% on an apnea and hypopnea event count when compared to a manually scored PSG.
- The ApLab and autoscored PSG were statistically equivalent on PPV and the ApLab was statistically superior on sensitivity.
- When compared to an industry standard AHI of 10, the ApLab produced a sensitivity of 89% with a PPV of 100% when compared to a manually scored PSG to determine if a patient has OSAS.
- The ApLab and PSG are equivalent on a breath-by-breath basis at all three time intervals.
- The ApLab provides a complete record of breathing to confirm the AHI scoring.

The safety results are:

- Nine patients wore the ApLab for an average of 4.46 hours with no device related adverse effects. There were no abnormal vital signs related to the ApLab. There were no early terminations.

**Conclusion:**

The performance tests and clinical trials completed on the ApLab demonstrate substantial equivalence to the predicate devices. The safety and effectiveness is demonstrated by the tests confirming accuracy of the recorded data to the product specifications and comparison to the predicate device clinical trial results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2003

Bradley Jeffries MD, MS
Vice President
Sector Medical Corporation
320 Northpoint Parkway, Suite P
Acworth, Georgia 30102

Re: K030379
Trade/Device Name: ApLab Ventilatory Effort Recorder, Model 801D0030
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: June 13, 2003
Received: June 18, 2003

Dear Dr. Jeffries:

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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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**Indications For Use Statement**

ApLab is intended for use in recording respiratory nasal pressure during sleep. The device is intended for use as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's score.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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✓ Prescription Use