K023796

Summary of Safety and Effectiveness

MAR 0 3 2003

Date of Preparation: October 29, 2002

Submitter: Erich Jaeger GmbH
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Device Trade Name: MS PAED – BABY BODY

Device Common/Classification Name: The MS PAED – BABY BODY is an Erich Jaeger GmbH device classified under 73 CCM, "Plethysmograph, Pressure", per Regulation No. 868.1750.

Predicate Device: INFANT BODY TEST (K853390)

Intended Use:

The MS PAED – BABY BODY is a neonatal lung function measurement system that utilizes a bodyplethysmograph. It is intended to be used under the direction of a physician. MS PAED – BABY BODY may be used in the clinic, doctors office, or hospital. Patient population that may benefit from the use of this device include only babies and premature infants.
The MS PAED – BABY BODY, or any of the accessories supplied with it, is not to be used, alone or in combination, as a life support device, a life support system, or as a critical component in a life support device or life support system.

Devise Description:

The MS PAED – BABY BODY is a local moveable device for the determination of airway resistance, absolute lung volume at FRC and tidal breathing patterns of babies and infants. Equipped with a computer and the Baby-Bodyplethysmography program the software is extremely easy to use, allows you to very quickly make several measurements and tolerates less experienced operators. The operator is to be guided through the program.

The built in quality checks of the program prompt the user about a bad performed manoeuvre or an unacceptably low quality of the measurement.

The body plethysmography measurement is provided with a reanalysis mode, which means that the physician can modify all data whenever required thereby eliminating the need for patients to return for additional measurements.

Comparison to Predicate Device:

The MS PAED – BABY BODY is similar to the Jaeger INFANT BODY TEST as follows: it transduces physiological signals into electrical signals. Also, the recorded data is analyzed and presented graphically and numerically. Both devices record the same physiological parameters relevant to pulmonary disease.

Summary of Performance Testing:

Performance testing was conducted in the laboratory to confirm compliance to device specifications; all functions were verified to operate as designed and intended, and measured parameters met required ranges and accuracies.
Testing to internationally accepted standards for electrical safety and electromagnetic compatibility were performed; the MS PAED – BABY BODY complied with the requirements of these standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 3 2003

Erich Jaeger GmbH
C/O Mr. Earl Draper
SensorMedics, Incorporated
22705 Savi Ranch Parkway
Yorba Linda, California 92887-4645

Re: K023796
Trade/Device Name: MS PAED-Baby Body
Regulation Number: 868.1750
Regulation Name: Pressure Plethysmograph
Regulatory Class: II
Product Code: CCM
Dated: February 18, 2003
Received: February 21, 2003

Dear Mr. Draper:

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, 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

510(k) Number: K023796

Device Name: **MS PAED - BABY BODY**

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K023796

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

(Optional Format 1-2-96)