K991087

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510(k) SUMMARY
HANNAH Wireless Vital Signs Monitor
March 29, 1999

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k), premarket notification was in accordance with 21 CFR 807.87.

1. Applicant/Submitter

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5910 N. Central Expressway, Suite 1775
Dallas, TX 75206

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Consultant
Joel S. Faden, Ph.D., Inc.
11605 Hitching Post Lane
Rockville, MD 20852

2. Name of Device

Trade Name: HANNAH Wireless Vital Signs Monitor
Common/Usual Name: Infant Apnea Monitor
Classification Name: 21 CFR 868.2375 "Breathing Frequency Monitor"

3. Legally Market Predicate Devices

The HANNAH system is an infant apnea monitor, which is substantially equivalent[1] to legally marketed devices, including the following:

- EdenTec 2000W (applicant: EdenTec; K844327, K871302, K884614, K901060)
- Monitron (applicant: American Health Products, Inc.; K874148)
- Model AMI Infant Central Apnea/Heart Rate Monitor (applicant: Aequitron Medical, Inc.; K961972)
- Respiration Monitor Type MR-10 (applicant: New Dimensions In Medicine, Inc.; K822077)

[1] Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to refer to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. (Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355))

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4. Indications for Use

The HANNAH Wireless Vital Signs Monitor is indicated for the continuous monitoring of an infant's heart rate, respiration rate, and occurrences of central apnea in home, hospital and other environments.

5. Device Description and Substantial Equivalence

The HANNAH system is an infant apnea monitor, which is substantially equivalent to legally marketed devices. The HANNAH system includes features incorporated in legally marketed devices. Like most legally marketed infant apnea monitors, the HANNAH incorporates sensors and alarms for monitoring both breath and heart rate. Like most legally marketed infant apnea monitors, the HANNAH system monitors heart rate using a 3-lead ECG measurement.

The HANNAH system has the same technological characteristics as legally marketed devices. Because lead wires connected to the infant present a documented risk for strangulation and electrocution, and because lead wires are the source of a substantial majority of the false alarms associated with wired monitors, the decision was made to use radio frequencies to transmit the monitoring information from infant-placed sensors to the central unit. Further, since the more common method of monitoring, impedance pneumography, is highly susceptible to false readings due to interference with cardiac signals and motion artifacts, respiration is monitored using a pressure sensor instead.

The manufacture, design and clinical and laboratory testing of the HANNAH system, and the information provided in the 510(k) conformed, where applicable, to FDA guidelines, as well as proposed and recognized standards. In particular, the HANNAH system conforms, where applicable, to FDA's "Performance Standard for the Infant Apnea Monitor" (proposed), FR Tuesday, February 21, 1995, 9762 (vol. 60, no. 34). Further, the device was tested, where applicable, in accordance with IEC 601-1, AAMI EC-13, and other recognized standards. Lastly, a clinical study of the device was conducted by an independent contract research organization in order to evaluate the HANNAH monitor's clinical performance relative to a legally marketed predicate device. The information provided in the 510(k) demonstrates the substantial equivalence of the HANNAH system to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2000

Mr. Joshua A. Adler
iLife Systems, Inc.
5910 North Central Expressway
Suite 1775
Dallas, TX 75206

Re: K991087
Hannah Wireless Vital Signs Monitor
Regulatory Class: II (two)
Product Code: 73 FLS and BZQ
Dated: November 2, 1999
Received: November 3, 1999

Dear Mr. Adler:

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,

Nancy C Brogdon for

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications For Use

Device Name: HANNAH Wireless Vital Signs Monitor

Indications For Use: The HANNAH Wireless Vital Signs Monitor is indicated for the continuous monitoring of an infant's heart rate, respiration rate, and occurrences of central apnea in home, hospital and other environments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K 991087