MAY 13 2002 K021246

510(k) SUMMARY
(as required by 807.92(c)

Submitter of 510(k): Sensidyne, Inc.
16333 Bay Vista Drive
Clearwater,
Florida, 33760

Contact Person: George Mason

Date of Summary: 4/17/02

Trade Name: SensAid

Classification Name: Oximeter (Accessory)

Predicate Device:
The Sensors listed below are similar in design, composition and function to the Sensaid sensor cleared by the FDA on Sensidyne's submission 510(k) K011974 and will be used as the predicate device for this submission. All sensors are used in conjunction with Disposable Positioning Tape (DPT Tape) which was cleared for sale by the FDA on Sensidyne's submission 510(k) K011974.

Predicate Device	New Sensor Model	Modification
RC-OHM20-10	RC-NVA30-10	Connector change 9 pin Hypertronix to 7 pin Hypertronix
RC-OHM20-10	RC-CSI40-10	Connector change 9 pin Hypertronix to 5 pin Limo
RC-OHM20-10	RC-BCI50-3	Connector change 9 Pin Hypertronix to DB9

Device Description:
The SensAid SpO_2 Sensors measure oxygen saturation (SpO_2), pulse rate, and plethysmographic pulse wave. The self-adhesive, latex free Disposable Positioning Tape (DPT) accessories quickly, comfortably, and securely attach to a patient. When a DPT is properly positioned on the patient and the SpO_2 Multi-Site Reusable sensor is connected to the DPT, the sensor light emitting diodes and detector are aligned to ensure proper sensor performance.

Indications For Use:
The intended use for the SensAid SpO_2 sensors is the same as the predicate sensors, i.e. compatible oximeter sensors are indicated for non-invasive monitoring of patient oxygen saturation (SpO_2), pulse rate, and plethysmographic pulse wave.
The SensAid sensors can be used for Adult, Pediatric and/or Neonate/Infant applications with the appropriate DPT accessory.

Technological Characteristics:
The SensAid and predicate oximeter sensors use two LED's (light emitting diodes) as light sources: a red LED typically 660nm peak emission (a wavelength of maximum discrimination between oxyhemogloben and reduced hemoglobin), and an infrared LED (typically in the peak emission range of 880nm to 940nm, varying by manufacturer). These light sources are sequentially pulsed into the tissue, and the light passing through the tissue for each wavelength is received by the photodiode, which converts the light intensity to a measurable electrical current.

Clinical Testing:
A desaturation study was completed by an independent research laboratory. The study provided a comparison between the SensAid System and the predicated devices. The data obtained from the study indicated that no significant deviation exists between the SensAid SpO_2 sensors and the respective predicate devices.

Conclusion:
Comparison of the data obtained from performance and clinical testing prove that the SensAid System is substantially equivalent to the predicate devices.

George Mason
QA and Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2002

Sensidyne, Inc.
c/o Mr. George Mason
16333 Bay Vista Drive
Clearwater, FL 33760

Re: K021246
Sensaid Pulse Oximeter Sensors, Models #RC-NVA30-10, #RC-CSI40-10, and #RC-BCI50-3
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: April 18, 2002
Received: April 19, 2002

Dear Mr. Mason:

This letter corrects our substantially equivalent letter of May 13, 2002 regarding the indications for use of your device. Our letter incorrectly limited your device to use in military environments.

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 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number: K021246

Device Name: SENSAID

Indications For Use:

Non-invasive monitoring of patient oxygen saturation (SpO_2), pulse rate, and plethysmographic pulse wave.
The SensAid sensors can be used for Adult, Pediatric and/or Neonate/Infant applications with the appropriate Disposable Positioning Tape (DPT) accessory.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021246

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

(Optional Format 1-2-96)