K111013 P1/2

DEC 19 2011

510(k) Summary

Submitted by	Sandhill Scientific, Inc. 9150 Commerce Center Circle, #500 Highlands Ranch, CO 80129
Contact Person	Lewis Ward L.W. Ward and Associates, Inc. 4655 Kirkwood Court Boulder, CO 80301 303-530-3279 lwward@qwest.net
Date Prepared	3-25-11
Device Trade Name	ACEM
Common Name	Sensor Pac, signal acquisition
Regulation Number	870.2780 Cardiovascular (plethysmograph) 876.1735 Gastroenterology (electrogastrography)
Classification Name	Plethysmograph, Product Code JOM System Electrogastrography (EGG), Product Code MYE
Intended Use	Plethysmography Module: The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography. Electrogastrography (EGG) Module: A device that receives, records, and produces a visual display of the myoelectrical signal produced by the stomach as an aid to diagnosis of various gastric disorders.
Technological Characteristics	The ACEM is an electronic accessory signal acquisition device. The ACEM includes five (5) signal conditioning circuits: respiration, plethysmograph, ECG and two channels of the EGG. Respiration and ECG have previous clearance under the InSight 510(k) K012232. The new plethysmograph accessory consists of a small, red LED placed against the finger and a photoelectric sensor to measure changes in the light intensity. The filter signal is amplified and digitized. The added EGG signal conditioning unit receives signals from the body through standard pad electrodes. The signals are filtered and digitized. Both the plethysmograph and EGG signals are forwarded to the Sandhill InSight System (K012232) for display.

Substantial Equivalence	The plethysmograph module is substantially equivalent to the Meridian McPulse device K023238. The EGG module is substantially equivalent to the 3CPM EGG machine K984637. Function, technology, and signals are equivalent. The ACEM is as safe and effective as the legally marketed devices.
Test Data	The ACEM has been demonstrated electrically safe through testing and meeting IEC 60601-1 and IEC 60601-1-2 safety standards. The ACEM does not raise new issues of safety or effectiveness. Bench data confirms the plethysmograph and EGG channels meet the product specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 19 2011

Sandhill Scientific, Inc.
c/o Mr. Lewis Ward
L.W. Ward and Associates, Inc.
4655 Kirkwood Court
Boulder, CO 80301

Re: K111013
Trade/Device Name: ACEM Sensor Pac
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: Class II (two)
Product Codes: FFZ, JOM, MYE
Dated: November 30, 2011
Received: December 7, 2011

Dear Mr. Ward:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K111013

Device Name: ACEM

Indications for Use:

Plethysmography Module:
The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography.

Electrogastrography (EGG) Module:
A device that receives, records, and produces a visual display of the myoelectrical signal produced by the stomach as an aid to diagnosis of various gastric disorders.

Prescription Use __X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

for bds

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111013