APR 16 2009

Chapter 15 510 (K) Summary

K090031

510 (k) Summary

Actherm Infrared Ear Thermometers and Probe Cover. The Trade models name ACT8000 Series and its Probe Cover medACCU2010. Because ACT8000 Series can be made with various functions, to clarify the difference, sometimes, the symbol or words, Dual scale, Backlight, Scan LED, W/O cover…will be added following the model number.

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Identification:

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Contact Person:

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Date Summary Prepared: 31 December, 2008

Manufacturing Site: Actherm Medical Corp.

103 Kengzi Section, Shenshan Road, Longgang

Shenzhen, Guangdong, CHINA

Device Name:

Infrared Ear Thermometer and its Probe Cover

Trade Model Name:

Actherm Infrared Ear Thermometer and its Probe Cover. The Trade models name ACT8000 Series and Probe Cover medACCU2010. Because ACT8000 Series can be made with various functions, to clarify the difference, sometimes, the symbol or words, Dual scale, Backlight, Scan LED, W/O cover…will be added following the model number.

Classification Name:

Clinical Electronic Thermometer (per 21 CFR 880.2910)

Predicate Device Information:

Braun GmbH,

Braun Thermoscan IRT4000 series

510 (k) number is K031928.

Device Description:

Actherm Infrared Ear Thermometers (Model ACT8000 Series) are electronic thermometers using a thermopile as the temperature sensor. The sensor's electric signal is then calculated and displayed by a MicroController. These thermometers display the temperature decimal. Model ACT8000 Series has the same indication for use. However, appearance difference exists between ACT8000 Series. Dual scale, Backlight, Scan LED, W/O cover, following with the model number indicates scale switchable, with Backlight, with Scan completed indicator, without probe cover.

The digital thermometer comprises: a thermopile for temperature sensing, a buzzer for sounding effect, a Micro Controller and a LCD display for calculating and displaying the target temperature digitally.

The system uses two 1.5V DC batteries for the power supply and the battery power is automatically checked by the MicroController and displayed in LCD if the battery is exhausted.

Actherm Infrared Ear Thermometers ACT8000 Series can be combined with accessories, weighting base and wall mount. For the weighting base, the whole set of body temperature measurement devices, including infrared ear thermometer, digital thermometer, and probe cover, can be put on it. For the wall mount, it can be fixed on the wall and the cradle of infrared ear thermometer can be put on this wall mount. Also, the probe cover boxes can be hanged on the hook that under the wall mount or put inside the cradle.

Intended Use:

Actherm Infrared Ear Thermometers ACT8000 Series have the same intended use as the predicate device. They are used to measure body temperature from auditory canal. This device is intended for household and hospital use on people of all age, and is used with or without probe cover.

Technological Characteristics:

Actherm Infrared Ear Thermometers ACT8000 Series have the same mode of operation, design principle, and biological specifications as the predicate device. For series variants, appearance difference exists between ACT8000 Series, Dual scale, Backlight, Scan LED, W/O cover, following with the model number indicates scale switchable, with Backlight, with Scan completed indicator, without probe cover.

Comparison to the 510(k) Predicate Devices:

The Actherm Infrared Ear Thermometers, Models ACT8000 Series are substantially equivalent to the following digital thermometers. Infrared Ear Thermometer Model Model IRT4520. Its 510(k) number is K031928.

The Actherm Infrared Ear Thermometers are similar in design and intended use to the predicates differing only in measurement range, function of memory, outlook and battery life. All products use the same temperature sensing element — a thermopile, an LCD display, MicroController, a buzzer and two 1.5V batteries.

Performance Data:

Actherm Infrared Ear Thermometers ACT8000 Series meet the ASTM Standard Specification for Infrared Thermometer for Intermittent Determination of Patient Temperature (ASTM E 1965-98: 2003), as well as EN60601-1, EN60601-1-2 and EN12470-5 requirements. Bench testing confirmed accuracy, precision and repeatability measurements specified in the labeling. For all body contacting materials, analysis is made that the identical materials have been used in other legally marketed devices under the same use conditions (See Chapter 9 Safety and Effectiveness Evaluation and Chapter 12 Biological Compatibility Report).

Substantial Equivalence:

Actherm Infrared Ear Thermometers ACT8000 Series have the same intended use, principles of operation, and similar technological characteristics as predicate devices. Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Actherm Infrared Ear Thermometers ACT8000 Series are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Hsinchu Science Park
Hsinchu 30078, TAIWAN

APR 16 2009

Re: K090031
Trade/Device Name: Actherm Infrared Ear Thermometer ACT8000 Series and Its Probe Cover medACCU2010
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: March 6, 2009
Received: March 9, 2009

Dear: Mr. Hsieh:

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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090031

Device Name: Actherm Infrared Ear Thermometer ACT8000 Series and its Probe Cover medACCU2010

Indications For Use:

Actherm Infrared Ear Thermometers ACT8000 Series are used to measure body temperature from auditory canal. This device is intended for household and hospital use on people of all age, and is used with or without probe cover medACCU2010.

Prescription Use _____ AND/OR Over-The-Counter Use __x__
(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)

Linda Hunsi for LCDR. Scott Colburn

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

510(k) Number: K090031