K083419
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Chapter 15 510 (K) Summary

JUL 16 2009

510 (k) Summary

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:

Actherm Inc.
6F, No.18, Jhanye 2nd Rd, Hsinchu Science Park, Hsinchu 30078, TAIWAN, R..O.C.

Contact Person:

Mr. Richard HSIEH

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Date Summary Prepared: July 8, 2009

Manufacturer: Actherm Inc.
6F, No.18, Jhanye 2nd Rd, Hsinchu Science Park, Hsinchu 30078, TAIWAN, R..O.C.

Device Name:

Digital Clinical Thermometer Probe Covers

Trade Name:

Actherm Digital Clinical Thermometer Probe Covers.
The Trade models name medACCU1010, medACCU1010-I and medACCU1020.

Classification Name:

Clinical Electronic Thermometer (per 21 CFR 880.2910)

Predicate Device Information:

BANTA HEALTHCARE GROUP, LTD (Rite Aid Brand)
Sanitherm Oral Disposable Thermometer Sheaths
510(k) Number is K983406

ACON LABORATORIES, INC.
ACON Digital Thermometer Probe Covers
510(k) Number is K063418

Device Description:

The Digital Clinical Thermometer Probe Covers medACCU1010 and medACCU1010-1 are manufactured in the same shapes and sizes. The only difference between them is medACCU1010-1 coated with lubrication; therefore it is only used for rectal measurements for digital thermometers. The Digital Clinical Thermometer Probe Covers medACCU1020 are manufactured in different shapes and sizes from medACCU1010 and medACCU1010-1. The disposable digital thermometer probe covers medACCU1010 and medACCU1020 are used for either oral or rectal measurements for digital thermometers.

Indications for Use:

The Actherm Digital Clinical Thermometer Probe Covers medACCU1010, medACCU1010-1 and medACCU1020 are accessories for digital thermometers, including the models of Actherm Digital Clinical Thermometers. They are indicated for use as barriers between digital thermometers and users' rectum or oral cavities to avoid the possible contamination and infection during temperature measuring. These probe covers are intended for single use when temperature taking.

Comparison to Predicate Devices:

The Actherm Digital Clinical Thermometer Probe Covers medACCU1010, medACCU1010-1 and medACCU1020 are substantially equivalent to the following predicate devices: Sanitherm Oral Disposable Thermometer Sheaths (K983406) and ACON Digital Thermometer Probe Covers (K063418).

Performance Data:

Actherm Digital Clinical Thermometer Probe Covers medACCU1010, medACCU1010-1 and medACCU1020 meet the ASTM Standard Specification for Clinical Thermometer Probe Covers and Sheaths (ASTM E 1104-98), as well as ISO 10993-1 biocompatibility testing.

Conclusion:

It is concluded that the Actherm Digital Clinical Thermometer Probe Covers medACCU1010, medACCU1010-1 and medACCU1020 are substantially equivalent to marked products, functions as intended, and with exception to the risks, which have been evaluated within the Hazard Analysis, no additional potential hazards have been found. The assessment of user benefit to health from use as intended is much higher than the probable risks of injury or illness. The study results also demonstrated that the Actherm Digital Clinical Thermometer Probe Covers medACCU1010, medACCU1010-1 and medACCU1020 are safe, effective and easy-to-use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Richard Hsieh
Actherm Incorporated
6F, No. 18 Jhanye 2nd Road
Hsinchu Science Park
Hsinchu
CHINA (TAIWAN) 30078

JUL 16 2009

Re: K083419
Trade/Device Name: Actherm Digital Thermometer Probe Covers, Models medACCU1010, medACCU1010-1, and medACCU1020
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 8, 2009
Received: July 14, 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.

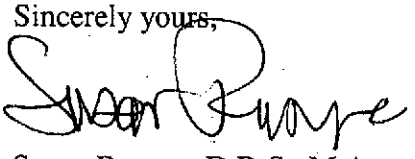
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., M.A.
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): K083419

Device Name: Actherm Digital Thermometer Probe Covers, Models medACCU1010, medACCU1010-1, and medACCU1020

Indications For Use:

The Actherm Digital Clinical Thermometer Probe Covers medACCU1010, medACCU1010-1 and medACCU1020 are accessories for digital thermometers, including the models of Actherm Digital Clinical Thermometers. They are indicated for use as barriers between digital thermometers and users' rectum or oral cavities to avoid the possible contamination and infection during temperature measuring. These probe covers are intended for single use when temperature taking.

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)

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

510(k) Number: K083419