FEB - 2 2007

5. 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.

The Assigned 510(k) number is K063418.

Submitter's Identification:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-875-8028
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Date Prepared: November 10, 2006

Contact Person:

Jinn-nan Lin, Ph.D.
V.P., Regulatory Affairs

Proprietary Name of the Device:

ACON™ Digital Thermometer Probe Covers

Common Name:

Digital Thermometer Probe Covers

Classification Name:

Class II §880.2910 Clinical Electronic Thermometer
(To be manufactured and marketed for consumer home use)

Predicate Device:

Sanitherm Oral Disposable Thermometer Sheaths
Banta Healthcare Group, LTD (Rite Aid Brand)
510(k) Number: K983406

Description:

The disposable digital thermometer probe covers are plastic coverings used for either oral or rectal measurements for digital thermometers. The product is non-sterile and contains latex.

Intended Use:

The ACON™ Digital Thermometer Probe Covers are intended for use as a barrier that is used as an accessory to oral or rectal measurements for digital thermometers, including the ACON 30 Second Reliable Digital Thermometer. These probe covers are non-sterile and intended for single use only.

Comparison to Predicate Devices:

The ACON™ Digital Thermometer Probe Covers are similar to the FDA-cleared Sanitherm Oral Disposable Thermometer Sheaths for Banta Healthcare Group, LTD (K983406) (Rite Aid Brand).

A Substantial Equivalence Comparison Table for the ACON Digital Thermometer Probe Covers and the Predicate Probe Covers is presented below:

	Sanitherm Oral Disposable Thermometer Sheaths (K983406)	**ACON Digital Thermometer Probe Covers**
Materials	Ethylene Methyl Acrylate Copolymer Film	Ethylene Vinyl Alcohol Copolymer Film
Latex Content	Latex-Free	Non Latex-Free
Sterility	Non-Sterile	Non-Sterile
Indication for Use	Oral or Rectal	Oral or Rectal
Usage	Single Use Only	Single Use Only

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ASTM E1104 as well as ISO 10993-5 and ISO 10993-10 biocompatibility testing.

Conclusion:

The performance characteristics of the ACON™ Digital Thermometer Probe Covers were verified by probe cover leakage test and probe cover validation test. Testing results indicate that the ACON™ Digital Thermometer Probe Covers are robust and can perform satisfactorily when used according to the "Indication for Use" statement specified in the package insert.

The laboratory testing results demonstrated a substantial equivalency in performance between the ACON™ Digital Thermometer Probe Covers and a legally marketed predicate device, Sanitherm Oral Disposable Thermometer Sheaths for Banta Healthcare Group, LTD (K983406) (Rite Aid Brand), with the same intended use and product features. The study results also demonstrated that the ACON™ Digital Thermometer Probe Covers 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

Dr. Jinn-Nan Lin
Vice President for Regulatory Affairs
ACON Laboratories, Incorporated
4108 Sorrento Valley Boulevard
San Diego, California 92121

FEB - 2 2007

Re: K063418
Trade/Device Name: ACON™ Digital Thermometer Probe Covers
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: January 11, 2007
Received: January 12, 2007

Dear Dr. Lin:

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 such 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 begin 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known):

Device Name: ACON™ Digital Thermometer Probe Covers

Indications for Use:

The ACON™ Digital Thermometer Probe Covers are intended for use as a barrier that is used as an accessory to oral or rectal measurements for digital thermometers, including the ACON 30 Second Reliable Digital Thermometer. These probe covers are non-sterile and intended for single use only.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

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

510(k) Number: K063418

Page 1 of 1