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 K060173.

Submitter's Identification:

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

Tel.: 858-535-2030
Fax: 858-535-2038

Date Prepared: January 19, 2006

Contact Person:

Edward Tung, Ph.D.
V.P., Regulatory Affairs

Proprietary Name of the Device:

ACON™ 30 Second Reliable Digital Thermometer/ACON Digital Thermometer Probe Covers

Common Name:

Thermometer, Electronic Thermometer, Predictive Thermometer

Classification Name:

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

Predicate Device:

BD Flexible Digital Thermometer, Model #524034
Becton, Dickinson and Company
510(k) Number: K935267

Description:

The ACON™ 30 Second Reliable Digital Thermometer consists of a temperature sensor within a metal probe and a Liquid Crystal Display all situated within a pen-like housing. The device is intended for the quantitative detection of body temperature, which can be obtained orally, under the arm, and / or rectally. It is intended to be sold over-the-counter for home use by laypeople without any professional training. And it could be used in hospitals as a substitute for the traditional mercury thermometer.

This device is intended for repeated use. Although the digital thermometer contains no sterile fittings, the user is recommended to clean the device prior to each use. A storage case or probe cover is provided to keep the metal probe tip covered when the thermometer is not in use. The ACON™ 30 Second Reliable Digital Thermometer can be used in conjunction with or without a disposable probe cover, when preferred.

Intended Use:

The ACON™ 30 Second Reliable Digital Thermometer and the ACON™ Digital Thermometer Probe Covers are intended for the quantitative detection of body temperature, which can be obtained orally, under the arm, and / or rectally. It is intended to be sold over-the-counter for home use by laypeople without any professional training. And it could be used in hospitals as a substitute for the traditional mercury thermometer.

Technological Characteristics:

Feature	Technical Specification
Measuring Time	30 seconds (Oral), 38 seconds (Underarm), 30 seconds (Rectal)
Beep	When thermometer is turned on and after completion of measurement
Measurement Range	89.6 - 109.2°F
Measurement Accuracy	± 0.2°F
Resolution	0.1°F
Memory	Last memory recall
Automatic Shut Off	After about 8 minutes
Display	3 digit LCD display
Operating Temperature	50 - 109.2°F
Storage Temperature	14 - 140°F
Operating/Storage Relative Humidity	10 - 95%
Waterproof	At tip area
Battery and Battery Life	1.5V LR41 battery; about 1,000 uses or 2 years battery life
Thermometer Dimensions	5.3" x 1.0" x 0.6"
Thermometer Weight	0.4 oz

Comparison to Predicate Devices:

The ACON™ 30 Second Reliable Digital Thermometer is substantially equivalent to the BD Flexible Digital Thermometer, Model #524034, K935267.

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

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

Compliance to applicable voluntary standards includes ASTM E1112, as well as EN 60601-1-2 and EN 12470-3 requirements and as well as ISO 10993 biocompatibility testing.

Guidance documents included the "FDA Guidance on the Content of Premarket Notification 510(k) Submissions for Clinical Electronic Thermometers".

Discussion of Clinical Tests Performed:

Controlled human clinical studies were conducted using the ACON™ 30 Second Reliable Digital Thermometer and the ACON™ Digital Thermometer Probe Covers. Clinical data were presented evaluating clinical bias, clinical uncertainty, clinical repeatability and clinical offset per ACON clinical test protocol for Digital Thermometer. Clinical study results indicate that the non-professional, inexperienced lay persons were able to obtain comparable body temperature measurement data when using the ACON™ 30 Second Reliable Digital Thermometer and a legally marketed digital thermometer, BD Flexible Digital Thermometer, Model #524034 (K935267). In addition, the lay persons also satisfied to the ease of the operation following the Instructions for Use in the Instruction Manual.

Conclusion:

The performance characteristics of the ACON™ 30 Second Reliable Digital Thermometer were verified by temperature range test, accuracy test, resolution test, cleaning test, battery condition test, operation environment test, storage environment test, indicating unit test, function safe test, mechanical safety test and Rite Aid disposable probe cover validation test. Testing results indicate that the ACON™ Digital Thermometer is robust and can perform satisfactorily when used according to the "Indication for Use" statement specified in the Instruction Manuals.

The laboratory testing results and lay person studies demonstrated a substantial equivalency on performance between the ACON™ 30 Second Reliable Digital Thermometer and a FDA-cleared Digital Thermometer, BD Flexible Digital Thermometer, Model #524034 (K935267), with the same intended use and product features. The lay person study results also demonstrated that the ACON™ 30 Second Reliable Digital Thermometer and ACON™ Digital Thermometer Probe Covers are safe, accurate and easy-to-use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2006

Dr. Edward Tung, Ph.D.
Regulatory Affairs
Acon Laboratories, Incorporated
4108 Sorrento Valley Boulevard
San Diego, California 92121

Re: K060173
Trade/Device Name: ACON™ 30 Second Reliable Digital Thermometer
ACON™ 30 Digital Thermometer Probe Covers
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: February 24, 2006
Received: March 1, 2006

Dear Dr. Tung:

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.

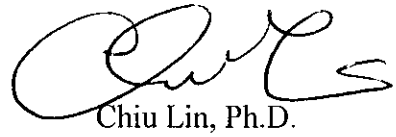
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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/dsma/dsmamain.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): K060173

Device Name: ACON™ 30 Second Reliable Digital Thermometer
ACON™ Digital Thermometer Probe Covers

Indications for Use:

The ACON™ 30 Second Reliable Digital Thermometer and the ACON™ Digital Thermometer Probe Covers are intended for the quantitative detection of body temperature, which can be obtained orally, under the arm, and/or rectally. It is intended to be sold over-the-counter for home use by lay persons without any professional training.

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)

[illegible] General Hospital
[illegible] Dental Devices

K060173