Attachment B4. 510(k) Summary

AUG 15 2011

510(K) SUMMARY

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

The Assigned 510(k) number is: K111974

1. Submitter's Identification:
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   Correspondence:
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   Regulatory Affairs Specialist
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   Date of submission: July 08, 2011

2. Device name:
   Proprietary name: ION HEALTH USB INSTA-SCAN THERMOMETER

   Regulatory information:
   A. Regulation section: 21 CFR 880.2910
   B. Classification: Class II
   C. Product Code: FLL, Clinical electronic thermometer
   D. Panel: General Hospital (80)

3. Intended Use:

ION HEALTH USB INSTA-SCAN THERMOMETER is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal on people of all ages and for use in the home. It also available to detect object's surface temperature including human skin.

4. Device Description:

The ION HEALTH USB INSTA-SCAN THERMOMETER is characterized by measuring human body temperature in the ear canal. It utilizes infrared technology to measure either infrared energy emitted from the eardrum and surrounding tissues when making a temperature measurement.

Substantial Equivalence Information:

A. Predicate device name:

FORA IR17 Ear Thermometer, model TD-1117

B. Predicate K number: K083299

C. Comparison with predicate:

The modified ION HEALTH USB INSTA-SCAN THERMOMETER has the following similarities to the predicate device:

- same operating principle,
- same fundamental scientific technology,
- incorporate the same basic circuit design,
- incorporate the same materials,
- same shelf life
- packaged using the same materials, and
- manufactured by the same process.

The modifications encompass:

- added the USB data transmission
- modification in the physical appearance
- increased memory storage capacity
- labeling change due to the modifications

5. Test Principle:
   The ear thermometer measures temperature by reading infrared radiation emitting from eardrum tissue. The small con-shape end of the thermometer is inserted into the ear canal, where the eardrum (tympanic membrane) and surrounding tissues give off heat. The thermometer converts it into a temperature value. This kind of temperature from the eardrum has been found to be a clinically reliable indicator of body core temperature.

6. Performance Characteristics:
   ION HEALTH USB INSTA-SCAN THERMOMETER has the same performance characteristics as the predicate device.

   A comparison of system accuracy performance demonstrated that the ION HEALTH USB INSTA-SCAN THERMOMETER, iH08 and the currently marketed FORA IR17 Ear Thermometer, TD-1117 (cleared under K083299) are substantially equivalent.

   Software verification and validation, performance and safety tests confirmed that the performance, safety and effectiveness of the ION HEALTH USB INSTA-SCAN THERMOMETER are equivalent to the predicate device.

7. Conclusion:
   Based on the information provided in this submission, the ION HEALTH USB INSTA-SCAN THERMOMETER is substantially equivalent to the predicate FORA IR17 Ear Thermometer, model TD-1117.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
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AUG 15 2011

Re: K111974
Trade/Device Name: ION Health USB Insta-Scan Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: August 2, 2011
Received: August 4, 2011

Dear Mr. Hsu:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
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Center for Devices and
Radiological Health

Enclosure

Attachment B3. Indications for Use

Indications for Use

510(k) Number: K111974

Device Name: ION HEALTH USB INSTA-SCAN THERMOMETER

Indications for Use:

The ION HEALTH USB INSTA-SCAN THERMOMETER is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal on people of all ages and for use in the home. It also available to detect object's surface temperature including human skin.

Prescription Use _____ And/Or Over the Counter Use __X____.
(21 CFR Part 801 Subpart D) (21 CFR Part 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
Office of Device Evaluation (ODE)
510(k) _____

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

510(k) Number: K111974