K101912

5. 510(k) Summary

[as required by 807.92(c)]

A. Applicant:

-Company name: HuBDIC Co., Ltd
-Address: 195-42, Anyang 7-dong, Manan-gu, Anyang-si, Gyeonggi-do, Korea (zip. 430-815)
▶ TEL : +82-31-441-8637
▶ FAX : +82-31-442-4994
▶ http://www.hubdic.com
-Contact person: **Peter Chung** 412-687-3976
-Date: June 28th, 2010

B. Proprietary and Established Names:

Trade Name: The Infrared Forehead Thermometer, FS-300&301

NOV 10 2010

Common Name: Clinical Electronic Thermometer
Regulation Name: Clinical Electronic Thermometer
Regulation Number:880.2910
Regulatory Classification: II
Product Code: FLL

C. Predicate device: Sensor touch (K011291)

D. Device Description

The Infrared Forehead Thermometer, Model/type FS-300&301 is an electronic thermometer using an infrared sensor (thermopile) to measure forehead temperature, then get a reading and display it on the LCD.

Its operation is based on measuring the natural thermal radiation emanating from the forehead and the adjacent surfaces.

This product is an Infrared Forehead Thermometer with measuring room temperature and relative humidity.

E. Intended use

The **Infrared Forehead Thermometer, FS-300&301** is intended for intermittent measurement of human body temperature in people of all ages.

F. Technological Characteristics:

To increase the accuracy, body temperature is measured 5,000 times in one second instantly and displays highest temperature on the LCD.
Purpose of measuring body temperature is to check body condition by measuring correct temperature in important part of body and both measured room temperature and relative humidity are to show environmental conditions.
In case of Forehead measurement, this product searches the highest temperature from the forehead to the temple. The temperature of the artery between the forehead and the temple that emits thermal infrared from the inner shin to the exterior body is scanned continuously while the measurement button is pressed down

G. Performance (Safety and Effectiveness Information)

The Infrared Forehead Thermometer, FS-300&301 has been manufactured and tested to meet the safety requirements of IEC. The Infrared Forehead Thermometer, FS-300&301 complies with IEC 60601-1 Medical electrical equipment - Part 1: General requirements for safety and IEC 60601-1-2:2001, Medical electrical equipment - Part 1: General requirements for safety - Collateral standard: Electromagnetic compatibility -Requirements and tests.

I. Conclusion:

The performance tests demonstrated that The Infrared Forehead Thermometer, FS-300&301 is as safe, as effective and performs in a substantially equivalent manner to the predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Hubdic Company, Limited
C/O Mr. Peter Chung
300 Atwood
Pittsburgh, Pennsylvania 15213

NOV 10 2010

Re: K101912
Trade/Device Name: The Infrared Forehead Thermometer, FS-300&301
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: October 8, 2010
Received: October 20, 2010

Dear Mr. Chung:

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.

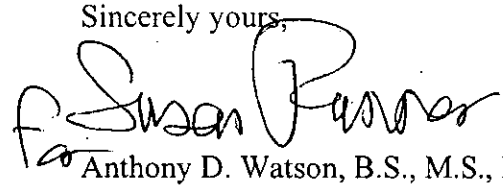
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



for Anthony D. Watson, B.S., M.S., M.B.A.
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): K101912

Device Name : **The Infrared Forehead Thermometer, FS-300&301**

NOV 10 2010

Indications For Use:
The Infrared Forehead Thermometer, FS-300&301 is intended for intermittent measurement of human body temperature in people of all ages.

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

11/4/2010

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

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