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File No: WMI-04-IR-T-FDA-05
Version: 1.1

JUL 22 2010

510(k) SUMMARY

IR Ear/Forehead thermometer, K ( )

Date of Submission: 01/20/2009

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1. Proposed Device:

Trade Name:	IR Ear/Forehead thermometer
Classification Name:	Clinical electronic thermometer
Regulation Number:	21 CFR 880.2910
Product Code:	FLL
Device Class:	II

2. Predicate Device:

Legally Marketed Device:	Infrared Thermometer Model:FDIR-V1
510(k) Number:	K052849
Manufacturer:	FAMIDOC TECHNOLOGY CO., LTD

3. Description of Proposed Device:

IR Ear/Forehead thermometer, which includes models DX6635, DX6637, TH1081 and TH1091, are a hand-held, reusable, battery operated device that can measures human body temperature by two ways:

- On forehead, the skin temperature on people's forehead
- In ear, the tympanic temperature in people's ear

The working principle based on infrared sensor technology. It utilizes infrared technology to receive infrared energy emitted from the eardrum or the surface of the object and convert to a voltage. The voltage value is responsible with the different temperature between the target object and infrared sensor. Then MCU will convert this value to digital data by an analog to digital (A/D) circuit. This data will be changed to the finalized temperature data by algorithms and displayed on LCD.

4. Proposed Device Intended for Use Statement:

Device Name:

IR Ear/Forehead thermometer, Model: DX6635, DX6637, TH1081, TH1091

Indications for Use:

The device is intended for the intermittent measurement and monitoring of human body temperature by consumers in the home.

5. Technological Characteristics and Substantial Equivalence

Both the IR Ear/Forehead thermometer and the Predicate device thermometer have the same intended use and fundamental technology. A side-by-side comparison of the IR Ear/Forehead thermometer and the cited predicate devices is included in the 510(k) submission. The IR Ear/Forehead thermometer is substantially equivalent to the technological features as the predicate devices.

Basic technological characteristics, new device vs. Predicate device

		New device	Predicate device
1	510K#	K	K052849
2	Device Name	IR Ear/Forehead thermometer Mode: DX6635, DX6636, TH1081, TH1091	Infrared Thermometer Mode: FDIR-V1
3	Manufacturer	Shenzhen Dongdixin Technology Co., Ltd.	FAMIDOC TECHNOLOGY Co., Ltd
4	Measurement temp range	32.0～42.9℃ (89.6～109.2℉)	32.0～42.9℃ (89.6～109.2℉)
5	Accuracy	35.5℃ (95.9℉) ～42.0℃ (107.6℉) ±0.2℃ (0.4℉), Other ±0.3℃ (0.5℉)	35.5℃ (95.9℉) ～42℃ (107.6℉) ±0.2℃ (0.4℉), Other ±0.3℃ (0.5℉
6	Ambient range	10℃～ 40℃ (50.0℉～104.0℉) for Ear 15℃～ 40℃ (59.0℉～104.0℉) for Forehead	10℃～ 40℃ (50.0℉～104.0℉)
7	Storage range	-20℃～ 55℃ (-4℉～ 131℉)	-25℃～ 55℃ (-13℉～131℉)
8	Display type	LCD	LCD
9	Activation	Scan button	Scan button
10	Power requirements	3V DC	3V DC
11	Classification	Clinical Electronic thermometer Class II 21 CFR 880.2910	Clinical Electronic thermometer Class II 21 CFR 880.2910

6. Performance Summary:

The device conforms to applicable standards included ASTM E1965-98 (2003), IEC 60601-1, and IEC 60601-1-2 requirements.

7. Conclusions:

IR Ear/Forehead thermometer, which includes models DX6635, DX6637, TH1081 and TH1091, has the same intended use and similar technological characteristics as the predicate device. Moreover, bench testing, safety report and Risk Analysis Report documentation supplied in this submission demonstrates that the difference in their technological characteristics do not raise any new question of safety or effectiveness. Thus, the IR Ear/Forehead thermometer is substantially equivalent 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

Shenzhen Dongdixin Technology Company, Limited
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

JUL 22 2010

Re: K100488
Trade/Device Name: IR Ear/Forehead Thermometer, Model: DX6635, DX6637, TH1081, TH1091
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: June 30, 2010
Received: July 15, 2010

Dear Mr. Devine:

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, 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

Caretalk®

File No: WMI-04-LT3000-FDA-04
Version: 1.1

Indications for Use

510(k) Number ( ):

Device Name:

IR Ear/Forehead thermometer, Model: DX6635, DX6637, TH1081, TH1091

Indications for Use:

The device is intended for the intermittent measurement and monitoring of human body temperature by consumers in the home.

Prescription Use_____ AND/OR Over-The-Counter Use _√__
(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)

for RZC July 22, 2010
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100488