1.3 510(k) SUMMARY

(P1256)

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510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K081256

Manufacturer:

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Date of Submission:

8/Oct/2007

Classification name:

Clinical Electronic Thermometer / Class II

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Proprietary Name:

Wireless Body Temperature Monitor/ BTM-D1X series (BTM-D1C, D, E, F, G & H)

Common name:

Wireless Body Temperature Monitor

Regulatory Reference:

21 CFR 880.2910

Predicate Device:

Rio Flexon Technology Co., Ltd

BTM-D1A/ Monitor Ear Thermometer, K062445

Intended Use:

The Wireless body temperature monitor, model BTM-D1x series are the battery-operated electronic devices with intended use of measuring human ear temperature precisely and continuously monitors armpit temperature via wireless signal transmission of measuring result. This device is reusable and intended for ear temperature measurement as well as the armpit temperature monitor for the person above two years old.

Device Description:

The Wireless body temperature monitor, BTM-D1X series include the BTM-D1C, D, E, F, G and H, which are the battery-operated electronic devices with intended to be worn at left arm to monitor the armpit temperature continuously. In addition, BTM-D1C has additional function of ear thermometer.

The device is composed of two operational parts, the receiver and armband. The receiver is the main operation unit on which the ear thermometer, the measuring circuit, LCD display control circuit and the main operation keys are included. And the armband was designed and constructed with the thermo sensor and the signal communication unit. For the monitoring operation, both receiver and armband shall be switched on. Sooner after these two parts are switched on, the wireless signal communication will be set up between receiver and armband. The temperature monitoring signal measured at armpit will be continuously indicated on the LCD of receiver every 12 sec.

In addition to the continuous armpit temperature monitoring, the user can also operate the functional key on receiver to take temperature measurement on ear any time if needed. The LCD will be returned to armpit temperature monitor after 30 sec.

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This system uses a 3.0V DC battery for operation of complete system. Whenever the battery is low, the MCU circuit will detect the low battery condition automatically, and displays "Low battery" in LCD display. Regarding the performance of BTM-D1X series, it was designed and verified according to the US standard ASTM E1112-00 and ASTM E1965-02.

Comparison to Predicated Devices:

Here the predicated device is BTM-D1A/ Monitoring Ear Thermometer, K062445 which BTM-D1x series is completely expanding from the predicated device, BTM-D1A. BTM-D1A has ear thermometer function and armpit temperature monitoring function. And BTM-D1x series include 6 models, BTM-D1C/D/E/F/G &H; BTM-D1C has ear thermometer function and armpit temperature monitoring function which is the same as the predicated device; the rest of models, BTM-D1D～H, only has armpit temperature monitoring function. The main difference between BTM-D1x series with the predicated device BTM-D1A is the appearance different only. The function and the software are substantially equivalent in safety and effectiveness to the K062445 Monitoring Ear Thermometer, BTM-D1A. The table below has comparison between predicated device, BTM-D1A, and the BTM-D1X series.

Element of comparison	BTM-D1A (Predicated Device)	BTM-D1C (BTM-D1X series)	BTM-D1D ～ H (BTM-D1X series)
Ear Thermometer type	Infrared tympanic thermometer	Infrared tympanic thermometer	N/A
Intended use	Intended use of measuring human ear temperature precisely and continuously monitors armpit temperature via wireless signal transmission of measuring result. This device is reusable and	Intended use of measuring human ear temperature precisely and continuously monitors armpit temperature via wireless signal transmission of measuring result. This device is reusable and intended for ear temperature	This device is intended to continuously monitor armpit temperature via wireless signal transmission of measuring result. The device is

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	intended for ear temperature measurement as well as the armpit temperature monitor for the person above two years old.	measurement as well as the armpit temperature monitor for the person above two years old.	intended to be used for two years old above.
Brand Name	Rio Flexon	Rio Flexon	Rio Flexon
Signal processing and display	Wireless 2.4G transmission & display on LCD screen of monitor	Wireless 2.4G transmission & display on LCD screen of monitor	Wireless 2.4G transmission & display on LCD screen of monitor
Power requirements of Armband	3V / CR2032 Lithium	3V / CR2032 Lithium	3V / CR2032 Lithium
Power requirement of Receiver	AAA battery x 2pcs	AAA battery x 2pcs	AAA battery x 2pcs
Temperature range	25℃ ~ 43℃	25℃ ~ 43℃	25℃ ~ 43℃
Ambient temperature	15℃ ~ 42℃ (with 95% RH humidity)	15℃ ~ 42℃ (with 95% RH humidity)	15℃ ~ 42℃ (with 95% RH humidity)
Storage condition	-20℃ ~ 50℃ (with 95% RH humidity)	-20℃ ~ 50℃ (with 95% RH humidity)	-20℃ ~ 50℃ (with 95% RH humidity)
Accuracy for armpit temperature	± 0.1℃	± 0.1℃	± 0.1℃
Accuracy for ear temperature	± 0.2℃ for 36℃ ~ 39℃; ± 0.3℃ for the others	± 0.2℃ for 36℃ ~ 39℃; ± 0.3℃ for the others	N/A
Monitoring time	24 hours	24 hours	24 hours
components	1. Receiver IC#: HT-49R50 2. Armband IC#: HT-46R52 3. Ear temperature measuring module	1. Receiver IC#: HT-49R50 2. Armband IC#: HT-46R52 3. Ear temperature measuring module	1. Receiver IC#: HT-49R50 2. Armband IC#: HT-46R52 3. RF transmission

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	4. RF transmission module (2.4GH)	4. RF transmission module (2.4GHz)	module (2.4GHz)
Sensor	SENTECH sensor	SENTECH sensor	SENTECH sensor
Electrical safety standard	EN 60601-1	EN 60601-1	EN 60601-1
EMC conformity	EN 60601-1-2 & FCC	EN 60601-1-2 & FCC	EN 60601-1-2 & FCC
Conformity of Bio-compatibility for the skin contact material (Armband)	ISO 10993 **Cytotoxicity** / Negative **Sensitization** / Negative **Primary skin irritation** / Negative	ISO 10993 **Cytotoxicity** / Negative **Sensitization** / Negative **Primary skin irritation** / Negative	ISO 10993 **Cytotoxicity** / Negative **Sensitization** / Negative **Primary skin irritation** / Negative
Measuring location	Ear & armpit	Ear & armpit	Armpit

Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence

Compliance to applicable voluntary standards includes ASTM E1112:2000, ASTM E1965:2002, as we as EN 60601-1 and EN 60601-1-2 requirement. All of the required conformity reports were included on the 510(k) submission documents.

Discussion of clinical report for measurement accuracy

Since the ear temperature measuring function of BTM-D1x series (only for BTM-D1C) is the integration of the chosen 510(k) clear model: Taidoc/TD-1107, the clinical report as included on Taidoc 510(k) submission (K050463) for measurement accuracy as required by ASTM E1965:2002 is still available for BTM-D1x series.

No additional clinical report is included on this 510(k) submission.

Performance Tests:

Test Performed	Laboratory
1. EN 60601-1	Electronics Testing Center, Taiwan
2. EN 60601-1-2/ EN 300 440-2 / EN 3011489-1/-3	Electronics Testing Center, Taiwan
3. ASTM/ E 1112-00	Rio Flexon Technology Co., Ltd

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4. ASTM/ E 1965-02	Taidoc Technology Corporation
5. Biocompatibility (ISO 10993)	Taiwan National Chung-Hsing University Lab.
6. FCC	Electronics Testing Center, Taiwan

Conclusions:

Regarding to above comparison table, BTM-D1x series has the same intended use as the predicated device K062445/ BTM-D1A-Monitoring Ear Thermometer. In fact, BTM-D1x series is completely expanding from the predicated device, BTM-D1A, which the function, the software and the intended use is the same as predicated device. BTM-D1x series include BTM-D1C, D, E, F, G and H. In which the BTM-D1C is with both function of ear thermometer and armpit temperature monitor as predicated device, BTM-D1A, and the rest of models of BTM-D, E, F, G and H are only with the function of armpit temperature monitor. According to the tests performed in this submission demonstrates that the difference in the submitted models could maintain the same safety and effectiveness as predicated device. In addition, the technological characteristics do not raise any new questions of safety and effectiveness. In general, the BTM-D1x series is expanded from BTM-D1A, the major function and software are the same except the product appearance. In other words, those appearance differences do not affect the intended use or alter the fundamental scientific technology of the device. In conclusion, BTM-D1x series is substantially equivalent to the predicated device approved as BTM-D1A/K062445.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2008

Rio Flexon Technology Company, Limited
C/O Mr. Jeffrey D. Rongero
Responsible Third Party Official
Underwriters Laboratories, Incorporated
12 Laboratory Drive
Research Triangle Park, North Carolina 27709

Re: K081256
Trade/Device Name: Wireless Body temperature Monitor / Model: BTM-D1C, D, E, F, G and H
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: May 15, 2008
Received: May 16, 2008

Dear Mr. Rongero:

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) 276-0120. 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

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4.4 Indication for Use

Indication for Use

510(k) Number (If know):

Device Name: Wireless Body Temperature Monitor / Model: BTM-D1C, D, E, F, G and H.

Indication for Use:

The Wireless Body temperature monitor, model BTM-D1x series (model BTM-D1C, D, E, F, G and H) is the battery-operated electronic devices with intended use of measuring human ear temperature precisely and continuously monitors armpit temperature via wireless signal transmission of measuring result. This device is reusable and intended for ear temperature measurement as well as the armpit temperature monitor for the person above two years old. In which, model BTM-D1C is with two functions of ear temperature measurement and armpit temperature monitor; the rest of models, BTM-D1D, E, F, G and H are only with the function of armpit temperature monitor.

Prescription Use _____ OR Over-The-Counter Use __V__

(Part 21 CFR 801 Subpart D) (21CFR 807 Subpart C)

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

(Division Sign-Off) Concurrence of CDRH, office of Device Evaluation (ODE)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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