Rio Flexon Technology Co., Ltd.

FEB 16 2007

K062445

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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: _____.

Submitter's Identifications:
Rio Flexon Technology Co., Ltd.
15F., No. 868-2, Jhong Jheng Rd., Jhonghe City, Taipei County 235, Taiwan, R.O.C.

Contact: Jeff Liao
Date of Summary Preparation: August 20, 2006

1. Name of the Device:
   Monitoring Ear Thermometer, model BTM-D1A.

2. Information of the 510(k) Cleared Device (Predicate Device):
   Taidoc Ear/skin/surface IR thermometer, model clever TD-1107 (K050463).
   Funai Wireless thermometer, model RT-901 (K003326).

3. Device Description:
   The Monitoring Ear Thermometer/model BTM-D1A is the combination device of ear thermometer and wireless temperature monitor intended to be worn at left arm to monitor the armpit temperature continuously.

   BTM-D1A 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 and is to be worn at left arm for the continuous armpit temperature monitor.

   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 he needs. The LCD will be returned to armpit temperature monitor as soon as the ear temperature measurement operation is completed.

   This system uses a 3.0V DC battery for operation of complete system. Whenever the battery is low, the ASIC circuit will detect the low battery condition automatically, and displays 'Low battery' in LCD display. Regarding the performance of BTM-D1A, it was designed and verified according to the US standard ASTM E1112-00 and ASTM E1965-02.

4. Intended Use:
   The Monitoring Ear Thermometer, model BTM-D1A is the battery-operated electronic devices with intended use of measuring human ear temperature precisely and continuously monitor 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 olds.

5. Comparison to the 510(k) Cleared Device (Predicate Device):
   - The wireless temperature monitoring function at armpit is to be compared to the Funai wireless thermometer model RT-9101 (K003326).
   - The ear thermometer function is to be compared to the Taidoc Ear/Skin/Surface IR thermometer model TD-107 (K050463).

6. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:
   Compliance to applicable voluntary standards includes ASTM E1112: 2000, ASTM E1965: 2002, as well as EN 60601-1, EN 60601-1-1, and EN 60601-1-2 requirement. All of the required conformity reports were included on the 510(k) submission documents.

7. Discussion of clinical report for measurement accuracy:
   Since the ear temperature measuring function of BTM-D1A 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-D1A.

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

8. Conclusions
   The Rio Flexon / Monitoring Ear Thermometer, model BTM-D1A has the same intended use and technological characteristics as the cleared device of Funai model RT-910I (K003326) and Taidoc model TD-1107 (K050463). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

   In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device. Therefore, it is reasonable to conclude that BTM-D1A is substantially requirement to the chosen predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jeff Liao
Official Correspondent
RIO Flexon Technology Company, Limited
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Jhonghe City Taipei County
Taiwan 235

FEB 16 2007

Re: K062445
Trade/Device Name: Monitoring Ear Thermometer / Model: BTM-D1A
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: January 26, 2007
Received: January 29, 2007

Dear Mr. Liao:

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.

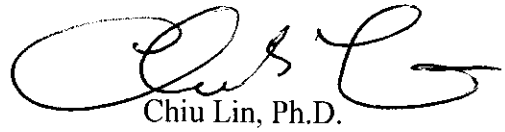
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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
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Enclosure

Indications For Use

510(k) Number (if known):

Device Name: Monitoring Ear Thermometer / Model: BTM-D1A.

Indications For Use:

The Monitoring Ear Thermometer, model BTM-D1A is the battery-operated electronic devices with intended use of measuring human ear temperature precisely and continuously monitor 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 olds.

Prescription Use ____ 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)

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