JUL 0 8 2014

Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K132761

1. Prepared Date: Aug. 26, 2013

2. Sponsor Identification

Raiing Medical Company
21 Huoju St, Beijing, China

Establishment Registration Number: 3010052175

Mr. Wu Wei
Title: General Engineer
Email: tjww@raiing.com
Tel: 86-10-64118658
Fax: 86-10-80115555 ext. 776445
Raiing Medical Company
21 Huoju St, Beijing, China

3. Submission Correspondent

Mr. Wu Wei
Title: General Engineer
Email: tjww@raiing.com
Tel: 86-10-64118658
Fax: 86-10-80115555 ext. 776445
Raiing Medical Company
21 Huoju St, Beijing, China

4. Proposed Device Identification

Proposed Device Name: Wireless Thermometer
Proposed Device Common Name: Thermometer

Regulatory Information:
Classification Name: Clinical Electronic Thermometer;
Classification: II;
Product Code: FLL;
Regulation Number: 21 CFR 880.2910;
Review Panel: General Hospital;

Intended Use Statement:
The Wireless Thermometer is a battery-operated electronic device with intended use of measuring and monitoring human armpit temperature continuously via wireless signal transmission of the measuring result. This system is reusable and intended for armpit temperature monitoring for persons over two years old.

5. Predicate Device Identification

510(k) Number: K121696
Predicate Device Name: Wireless Thermometer WTM-BT30-I
Manufacturer: Raiing Medical Company

6. Device Description

The wireless thermometer, WT701, which is the combination device of thermometer and Bluetooth communication unit intended to be worn at axilla to monitor the armpit temperature continuously.

For the monitoring operation, switch the thermometer on and stick the thermometer in the user's axilla. The thermometer will make a Bluetooth connection between the thermometer and the receiver automatically (User should setup Bluetooth properly on receiver). Then the thermometer starts to measures the body temperature by means of testing the NTC resistor's resistance value and calculates the body temperature every 4 seconds continuously and sends the temperature data to the receiver through

Bluetooth connection.

The wireless thermometer uses a CR2032 battery for operation. When the battery is low, internal circuit will detect the low battery condition automatically and send "low battery" signal through Bluetooth communication unit to receiver.

7. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC60601-1:2005 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2007 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests
FCC Part 15 Subpart C test FCC Part 15.247
ASTM E1112-00: 2006 Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature.
EN 12470-4: 2000+A1:2009 Clinical thermometers Part-4: performance of electrical thermometers for continuous measurement.
And the proposed device also conducted the performance test, which include Dimension Test, Weight Test, and accuracy transmission test under a complex electromagnetic environment.

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

ITEM	**Proposed Device WT701**	**Predicate Device K121696**
Product Code	FLL	FLL
Regulation No.	880.2910	880.2910
Class	Class II	Class II

Intended Use	The Wireless Thermometer is a battery-operated electronic device with intended use of measuring and monitoring human armpit temperature continuously via wireless signal transmission of the measuring result. This system is reusable and intended for armpit temperature monitoring for persons over two years old.	The Wireless Thermometer, model WTM-B530-I, is a battery-operated elected electronic device with intended use of measuring and monitoring human armpit temperature continuously via wireless signal transmission of the measuring result. This system is reusable and is intended for armpit temperature monitoring for persons over two years old.
Display Unit Specification	iOS device Display	LED and iOS device Display
Working voltage	DC3V	DC3.7V
Battery	The button battery 3.0 V, 210mAh	Internal 3.7V, 100mAh Li Battery
Measurement range	25 ℃～45 ℃	25 ℃～45 ℃
Accuracy	±0.05℃(35℃-38.5℃) ±0.1℃(25℃-34.99℃ and 38.51℃-45℃)	±0.1℃
Temperature unit	℃ or ℉	℃ or ℉
Signal transmission	Wireless 2.4G Bluetooth BLE	Wireless 2.4G Bluetooth 3.0
Receiver	iPhone 4S, iPhone 5, iPad(3rd generation), iPad(4th generation), iPad mini, iPod touch(5th generation)	iPod touch 4, iPhone 4, iPhone 4S, iPad, iPad 2, The new iPad
Valid transmission distance	Up to 5 meters	Up to 5 meters
Operating Temperature	5℃~40 ℃	5℃~40 ℃
Operating Humidity	15-85%	15-85%

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 8, 2014

Raiing Medical Company
Mr. Wei Wu
General Engineer
No.11 Huatong Rd
Beijing
CHINA

Re: K132761
Trade/Device Name: Wireless Thermometer, Model WT701
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: June 3, 2014
Received: June 6, 2014

Dear Mr. Wu:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132761

Device Name
Wireless Thermometer, Model WT701

Indications for Use *(Describe)*
The Wireless Thermometer is a battery-operated electronic device with intended use of measuring and monitoring human armpit temperature continuously via wireless signal transmission of the measuring result. This system is reusable and intended for armpit temperature monitoring for persons over two years old.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman -S
Date: 2014.07.08 11:26:01 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."