OCT 11 2012

Section 1 **510(k) Summary**

As required by 807.92

The assigned 510(k) Number is K121696

Sponsor	Raiing Medical Company No. 11, Huatong Rd., Beijing, China 102200 Mr. Wu Wei, General Engineer Tel:+86-10-64118658 Fax: +86-10-80115555 ext. 776445 Email: tjww@raiing.com
Submission Correspondent	Mr. Wu Wei Raiing Medical Company No. 11, Huatong Rd., Beijing, China 102200 Tel: +86-10-64118658 Fax: +86-10-80115555 ext. 776445 Email: tjww@raiing.com
Proposed Product	
Trade Name	Wireless Thermometer
Model	WTM-BT30-I
Product Code:	FLL
Regulation Number:	21 CFR 880.2910
Device Class:	Class II
Submission Purpose:	New Device
Predicate Device:	K100226/RIO FLEXON TECHNOLOGY CO., LTD.
Device Description	The proposed device is use to measure, monitor and record the body temperature in armpit, and transmits the data recorded to receiver for display by wireless (blue tooth) way in real time.
Test Conclusion	IEC 60601-1 IEC 60601-1-2 ASTM E1112-00

	FCC Part 15 Performance Test
SE Determination	The proposed device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the subject device is determined as safe and effectiveness. Please refer to the brief SE Comparison Table as following.
Intended Use/Indication for Use	The Wireless Thermometer, model WTM-BT30-I, 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 is intended for armpit temperature monitoring for persons over two years old.

Brief SE Comparison Table between the Proposed Device and Predicate Device

Comparison Elements		**Proposed Device**	**Predicate Device** (K100226)
Intended Use		The Wireless Thermometer, model WTM-B530-1, 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 is intended for armpit temperature monitoring for persons over two years old.	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 measurements as well as the armpit temperature monitor for the person above two years old.
Device Specifications		The proposed device has the similar device specification with the predicate device without new risk of safety and effectiveness.	
Material Specification		All materials used for skin-connecting are meet the requirements of FDA and the biocompatibility test has been conducted.	
Safety and Performance	Biocompatibility	Conformed to ISO 10993-1, ISO 10993-5, ISO10993-10, ISO10993-12.	Conformed to ISO 10993-1, ISO 10993-5, ISO10993-10, ISO10993-12.
	Electrical Safety	Conformed to IEC 60601-1	Conformed to IEC 60601-1
	Electromagnetic Compatibility	Conformed to IEC 60601-1-2 and FCC	Conformed to IEC 60601-1-2 and FCC
	Performance	Conformed to ASTM E1112	Conformed to ASTM E1112

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

Raiing Medical Company
Mr. Wu Wei
General Engineer
No. 11, Huatong Road
Beijing, China 102200

OCT 11 2012

Re: K121696
Trade/Device Name: Wireless Thermometer WTM-BT30-I
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 10, 2012
Received: September 10, 2012

Dear Mr. Wei:

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): k121696

Device Name: Wireless Themometer /Model: WTM-BT30-I

Indications For Use:

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.

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)

9/21/12

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

510(k) Number: K121696