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

August 21,2014

Shenzhen Belter Health Measurement and Analysis
Technology Company, Limited
Pang Ming
RA Manager
702, 704, Block C, Tsinghua Unis Science Park,
Langshan Rd, Hi-Tech Industrial Park (north),
Nanshan District, Shenzhen, Gangdong
CHINA 518057

Re: K140681
Trade/Device Name: Belter Infra-red Ear Thermometer, Models TE-66, TE-68, TE-79, TE-90, and TE-91
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Product Code: FLL
Regulatory Class: II
Dated: July 15, 2014
Received: July 21, 2014

Dear Mr. Ming:

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 Keith, M.S.
Division 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)*
K140681

Device Name
Belter Infra-red Ear Thermometer
Model: TE-66,TE-68, TE-79, TE-90, TE-91

Indications for Use *(Describe)*

The Belter Infra-red Ear thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal on people of all ages for home and professional use.

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)*

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."

Section 5 K140681 510（K）Summary

Date: 2014,1,15

Submitter Information

Name :Shenzhen Belter Health Measurement and Analysis Technology Co.,ltd
Address: 702、704，block C ,Tsinghua Unis science park,No.13 Langshan Rd,Hi-Tech Industrial park(north),Nanshan District,518057 shenzhen. People's Republic of China
Tel: +86-755-61869839
Fax: +86-755-61869122
Contact person: pang ming
E-mail: pangm@ebelter.com

Name of device

Trade name: Belter Infra-red Ear Thermometer
Model: TE-66,TE-68, TE-79, TE-90, TE-91
Common name: Belter Infra-red Ear Thermometer
Classification name: Thermometer, Electronic, Clinical
Production regulation: 21 CFR 880.2910
Product code: FLL

Predicate Device

Infrared Ear Thermometer THP Series (Radiant Innovation Inc,FLL,K111637)

Description

The Belter Infra-red Ear Thermometer is characterized by measuring human body temperature from the ear canal. It utilizes infrared technology to measure infrared energy emitted from eardrum tissue when making a temperature measurement.

Intended use

The Belter Infra-red Ear Thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal on people of all ages for home and professional use.

Summary of technological characteristics of device compared to the predicate devices (K111637), see the table1

Table 1

SE Comparisons	Subject device Present application	Predicate device K111637	comment

Intended Use& Indication for use	The Belter Infra-red Ear Thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal on people of all ages for home and professional use.	The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.	Similar
Measurement Range	32.0℃-42.2℃（89.6℉-108.0℉）	34.0°C ~42.2°C (93.2°F ~108.0°F)	Similar
Accuracy	±0.2℃ (36℃≤t<39) ; ±0.3℃other range	±0.2°C (0.4°F) within 35.5~42°C (95.9~107.6°F), ±0.3°C(0.5°F) other range	
Response time	1 sec.	1 sec.	same
Measurement place	ear	ear	same
Scale selection	℃/℉	C /°F	same
Display screen	LCD	LCD	same
Memory	10 sets	25 sets	Similar
Fever alarm	Yes	Yes	same
Disposable probe cover	No	MOLD RING W/PE FILM COVER	----
Backlight	optional	optional	Same
Buzzer	Yes	Yes	same
Auto power-off while no operation	Yes	Yes	Same
Power supply	2 x AAA	CR2032 *1pcs	---
Conformance standard	ISO80601-2-56(performance), EN60601-1(Safety), IEC60601-1-2(EMC) ISO 10993-1,5,10(Biocompatibility)	ISO80601-2-56(performance), EN60601-1(Safety), IEC60601-1-2(EMC) ISO 10993-1,5,10(Biocompatibility)	Same

Performance Data

Compliance to applicable standards includes ISO80601-2-56,as well as IEC 60601-1 ,IEC 60601-1-2 and IEC60601-1-11 requirements.

The bench test report of this submission shows the laboratory accuracy is 0.01~0.19℃, which is not greater than 0.2 ℃, and the clinical repeatability is 0.07 ~ 0.11℃,which is less than 0.3℃,so the accuracy of the device ,both bench and clinical, meets the requirements of ISO80601-2-56.

About the structural integrity of device item, the device has be done shock tests and broad-band random vibration test ,the result in bench test of this submission showed the device meets the requirement.

Conclusion

The Belter Infra-red Ear Thermometer, has the similar intended use and characteristics as the cleared device in K111637. Moreover, bench testing contained in this submission supplied demonstrate that the modification of Belter units, do not raise any new questions of safety or effectiveness. Thus, the subject device is substantially equivalent to the predicate device.