MAR 1 8 2014

K131210

510(k) Summary

1. Applicant

Applicant Name: SHENZHEN PUMP MEDICAL SYSTEM CO., LTD.
Address: 2/F West, M-7 Sinosteel Building, Maqueling Estate, Hi-Tech Industrial Park, Nanshan District, Shenzhen 518057, China

Contact person:
Name: Xie Qiongyu
Phone numbers: 86-0755-26710795
Fax numbers: 86-0755-26012025
E-mail: xieqy@bpump.com.cn

Date Prepared: 2013-04-20

2. Device information

- Trade name: Electronic Thermometer
- Model No.: TF3100, TF3101, TF3102
- Classification name: Thermometer, electronic, clinical (per CER 880.2910)
- Class: 2
- Regulation Medical Specialty : General Hospital
- Review Panel: General Hospital
- Product code: FLL- Clinical Electronic Thermometer
- Regulation Description: Clinical electronic thermometer
- Regulation Number: 880.2910

Indications for Use: It is intended for use in measuring temperature in the human body (Armpit or Oral).

Predicates

Digital thermometer Model MT Series
K-number: K062784
Product Code: FLL

Indications for Use:

The devices Model MT series (MT-201, MT-301, MT-402, and MT-403) are intended to measure the human body temperature in regular mode orally, rectally or under the arm, and the devices are reusable for clinical or home use on people of all ages.

Manufacture: SEJOY ELECTRONICS & INSTRUMENTS CO., LTD.

4. Description of the device

The body temperature is converted into electronic signal by the temperature sensor, and then the electronic signal is converted into LCD digital display.

The Electronic Thermometers TF3100, TF3101 and TF3102 have the same basic principles, main function, performance and intended use, and they are consistent in product structure and material.

5. Comparison to Predicate Devices

ELEMENT OF COMPARISON	Electronic Thermometer Model No.: TF3100, TF3101, TF3102 Manufacture: **SHENZHEN PUMP MEDICAL SYSTEM CO., LTD.**	Digital thermometer MT Series (**K062784**) Manufacture: **SEJOY ELECTRONICS & INSTRUMENTS CO., LTD.**
thermometer type	TF3100, TF3101, TF3102	MT-301
intended use(s)	It is intended for use in measuring temperature in the human body (Armpit or Oral).	The devices Model MT series (MT-201, MT-301, MT-402, and MT-403) are intended to measure the human body temperature in regular mode orally, rectally or under the arm, and the devices are reusable for clinical or home use on people of all ages.
components	Temperature sensor, liquid crystal display, battery and circuit of motherboard	
sensor	Thermistor	
signal processing and display	Using the resistance change of thermal resistor to detect body temperature, and displayed through the LCD.	
power requirements	DC3.7V Rechargeable Lithium Battery	One 1.5 V Button Battery model LR 41
Materials	ABS plastic and stainless steel	
temperature range	32.00°C ~ 42.00°C	32.00°C - 42.90°C
ambient temperature environment	+5°C ~ +40°C	10°C ~ 35°C
accuracy	0.05°C(35.30°C ~ 39.00°C) 0.1°C (< 35.30°C or > 39.00°C)	±0.1°C,35.5°C - 42.0°C ±0.2°C under 35.5°C or over 42.0°C
precision and repeatability	4 numerical digits, display in 0.01 degree increments	4 numerical digits, display in 0.01 degree increments
Response time	5 minutes	5 minutes
Water-proof	IP22	IP22

Reference Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, ISO 10993-5, ISO 10993-10, ASTM E1112-00	IEC 60601-1, IEC 60601-1-2, ISO 10993-5, ISO 10993-10, ASTM E1112-00

Comparing to the predicate, the subject devices used same the Measuring Principle, same electrical measurement technologic and same measurement site (Measuring on Armpit or Oral). The subject devices do not constitute a new intended use.

As a result, the subject device is Substantially Equivalent (SE) to the predicate which is US legally market device.

6. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence

Laboratory testing was conducted to validate and verify that Electronic Thermometer met all requirements of related international standards, including electrical safety, EMC, biocompatibility, specification. Results of these tests demonstrate compliance to the requirements of the bellow consensus standards.

Standard:
Electrical Safety and performance requirements: IEC 60601-1 ASTM E1112-00
Home-used medical equipment requirements and Environmental test: IEC 60601-1-11
Electromagnetic Compatibility Requirements: EN 60601-1-2
Biocompatibility Evaluation for the part contacted to patient ISO 10993-5, ISO 10993-10

7. Clinical Evaluation

Clinical evaluation of Electronic Thermometers has been conducted by SHENZHEN PUMP MEDICAL SYSTEM CO., LTD.

8. Conclusion

As stated above, the Electronic Thermometer (Models: TF3100, TF3101 and TF3102) have the same intended use and similar technological characteristics as the cleared devices of the digital thermometer MT series (K062784).

Moreover, the Electronic Thermometer (Models: TF3100, TF3101 and TF3102) comply with the appropriate medical device standards. Verification and validation test reports contained in this submission demonstrate that any differences in their characteristics do not raise any new questions of safety or effectiveness.

Furthermore, those engineering differences do not affect the intended use or alter the fundamental scientific technology of the cleared devices of the digital thermometer MT series (K062784).

As a result, Electronic Thermometers (Models: TF3100, TF3101 and TF3102) are safety and effective, and substantially equivalent to the earlier identified predicate devices.

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

March 18, 2014

SHENZHEN PUMP MEDICAL SYSTEM Company, Limited
C/O Ivy Chen
Shenzhen Huatongwei International Inspection Co., Ltd.
Keji Nan No.12 Road, Hi-tech Park
Shenzhen, Guangdong 518057
CHINA

Re: K131210
Trade/Device Name: Electronic Thermometer, Models TF3100, TF3101, TF3102
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: November 27, 2013
Received: March 13, 2014

Dear Ms. Chen:

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 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. 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,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting 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 on last page.

510(k) Number *(if known)*
K131210

Device Name
Electronic Thermometer, Models TF3100, TF3101, TF3102

Indications for Use *(Describe)*
It is intended for use in measuring human body temperature （Armpit or Oral）.

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
Date: 2014.03.18 09:36:56 -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."