



Food and Drug Administration
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January 15, 2016

Pinghu Sama Medical Packing Co., Ltd.
c/o Mr. Ray Wang
Beijing Believe Tech. Service Co., Ltd.
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No.5 Chaoyang Rd., Chaoyang District
Beijing, 100024
CHINA

Re: K152690

Trade/Device Name: Disposable Thermometer Probe Sheath

Regulation Number: 21 CFR 880.2910

Regulation Name: Clinical Electronic Thermometer

Regulatory Class: II

Product Code: FLL

Dated: December 15, 2015

Received: December 18, 2015

Dear Mr. Wang:

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" (21 CFR 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,

 Tina
Kiang -S

for 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

Indications for Use

510(k) Number (if known)

K152690

Device Name

Disposable Thermometer Probe Sheath

Indications for Use (Describe)

The Disposable Thermometer Probe Sheaths are intended for use as barriers between digital thermometers and users' oral cavities to avoid the possible contamination and infection during temperature measuring. The sheaths are non-sterile and intended for single use only.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – K152690

Date of Preparation: 9/17/2015

Sponsor Identification

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Identification of Proposed Device

Trade name: Disposable Thermometer Probe Sheath

Common Name: Thermometer Probe Covers and Sheaths

Model: Oral

Regulatory Information

Classification Name: Clinical Electronic Thermometer

Classification: 2

Product Code: FLL

Regulation Number: 880.2910

Review Panel: General Hospital

Proposed Predicate Device

K112289

Disposable Thermometer Covers and Sheaths

KANG ZE INDUSTRIAL Co., Ltd.

Intended Use Statement

The Disposable Thermometer Probe Sheaths are intended for use as barriers between digital thermometers and users' oral cavities to avoid the possible contamination and infection during temperature measuring. The sheaths are non-sterile and intended for single use only.

K152690 -510K Summary

Device Description

The Disposable Thermometer Probe Sheaths are used for oral measurements for digital thermometers. The products and packaging are non-sterile, not made with natural rubber latex, and intended for single patient use only.

The proposed device is a shell-like device, made of PE/EVA, use to cover the oral thermometer as barrier for avoiding possible contamination and infection during measurement of temperature. The device is covered by the paper (Medical Kraft Paper) at the top and bottom which to avoid unnecessary touch with the device before usage and will be removed from the device before use. The outer most packing material is carton box. Each outer packing contains 100 pieces of the device.

Subject and Predicate Device Comparison:

ITEM		Proposed Device-K112289	Predicate Device-K152690
Intended Use		The Disposable Thermometer Probe Sheaths are intended for use as barriers between digital thermometers and users' oral cavities to avoid the possible contamination and infection during temperature measuring. The sheaths are non-sterile and intended for single use only.	The Disposable Thermometer Covers and Sheaths are intended for use as barriers between digital or mercury thermometers and users' rectum or oral cavities to avoid the possible contamination and infection during temperature measuring. These covers and sheaths are non-sterile and intended for single use only.
OTC use		Yes	Yes
Basic Design		3 layer design (Bottom Side Paper + PE/EVA film + Top Side Paper); Removing paper before use;	3 layer design (Bottom Side Paper + PE/EVA film + Top Side Paper); Removing paper before use;
Device Materials Composition		PE/EVA	PE/EVA
Size		One size	Varied size
Thickness		23.5 um	NA
Outsider Dimension	Length	115 mm	120 mm
	Width	30 mm	33 mm
Available Dimension	Length	90 mm	88 mm
	Width	30 mm	29 mm
Density		0.87-0.88g/cm ³	N/A
Strength		Meet the requirements of ASTM 1104 Air Pressure of 8.4 kPa (1.2 psi) for 5 seconds	Meet the requirements of ASTM 1104

K152690 -510K Summary

Accuracy	Meet the requirements of ASTM E1104/E1112 ±0.3°C, Less than 38 °C; ±0.2°C, 35.8 °C to less than 37 °C; ±0.1°C, 37.0 °C to 39.0 °C; ±0.2°C, greater than 39.0 °C to 41.0 °C;	Meet the requirements of ASTM E1104/E1112
Color	None	None
Sterile	No	No

Discussion

The basic intended use is the same for both the predicate and subject device in that the device functions as an outer barrier to the thermometer. The predicate device is indicated for both oral and rectal thermometer whereas the subject device is only indicated for oral thermometers. Although small differences exist with predicate device in terms of dimension specification, whether the dimension differences affects temperature measuring accuracy of covered thermometers was evaluated. Performance testing for temperature accuracy was investigated per ASTM E1104/ASTM E1112, the test results showed compliance with the temperature accuracy requirements, thus the subject device has demonstrated it is substantially equivalent with the predicate device.

Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications to perform similarly and in a substantially equivalent manner to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

-ASTM E1104-98: Standard Specification for Clinical Thermometer Probe Covers and Sheaths

-ASTM E1112-00: Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature

-Bench Testing for the performance of Dimensions, Integrity

Conclusion: The Disposable Thermometer Probe Sheaths have demonstrated the product is similar in intended use and materials of construction as that of the predicate device. Performance testing showed it performs in a manner that is substantially equivalent to the legally marketed predicate device.