March 22, 2021

Shenzhen Juzhong Technology Co., Ltd
℅ Long Yang
CEO
Shenzhen Hlongmed Biotech Co., Ltd.
1201, Haosheng Business Center, 4096 Dongbin Road,
Nanshan
Shenzhen, Guangdong 518000
China

Re: K202009
Trade/Device Name: Probe Cover: JZ-KBT-001, JZ-KBT-002, JZ-KBT-005, JZ-KBT-007, JZ-KBT-008, JZ-KBT-009, JZ-KBT-010, JZ-KBT-015, JZ-KBT-025, JZ-KBT-026
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 30, 2021
Received: February 19, 2021

Dear Long Yang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Payal Patel
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202202

Device Name
Probe Cover
Model:JZ-KBT-001, JZ-KBT-002, JZ-KBT-005, JZ-KBT-007, JZ-KBT-008, JZ-KBT-009, JZ-KBT-010, JZ-KBT-015, JZ-KBT-025, JZ-KBT-026

Indications for Use *(Describe)*
The Probe Cover is intended for use as a barrier that is used as an accessory to oral or axillary for digital thermometers. This Probe Cover is non-sterile and is intended for single patient 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.

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

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K202009 510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Date of Summary: March 12, 2021

1. Submitter

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2. Contact Person

2.1 Primary Contact Person

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3. Proposed Device Information

Trade name: Probe Cover

Model:JZ-KBT-001, JZ-KBT-002, JZ-KBT-005, JZ-KBT-007, JZ-KBT-008, JZ-KBT-009, JZ-KBT-010, JZ-KBT-015, JZ-KBT-025, JZ-KBT-026

Common name: Disposable Thermometer Sheaths

Classification name: Clinical electronic thermometer

Review Panel: General Hospital

Product Code: FLL

Regulation Class: II

Regulation Number: 21 CFR 880.2910

4. Predicate Device Information

510(k) Number: K102508

Manufacturer: YU LONG SHENG TECHNOLOGY CO.,LTD

Trade Name: Yu Long Sheng Disposable Thermometer Sheath, Model YSL-01

Classification name: Clinical electronic thermometer

Review Panel: General Hospital

Product Code: FLL

Regulation Class: II

Regulation Number: 21 CFR 880.2910

5. Device Description

The Probe Cover is a plastic covering used for oral/axillary digital thermometer. This device is not made with natural rubber latex. Refer to user manual for the recommend thermometers that probe covers can be used with.

6. Intended use

The Probe Cover is intended for use as a barrier that is used as an accessory to oral or axillary for digital thermometers. This Probe Cover is non-sterile and is intended for single patient use only.

7. Comparison to Predicate Device

The Probe Cover have the similar intended use, similar technological characteristics as the following predicate device and are substantially equivalent with regards to safety and effectiveness.

K102508 Yu Long Sheng Disposable Thermometer Sheath, manufactured by YU LONG SHENG TECHNOLOGY CO.,LTD

The following table shows similarities and differences of technological characteristics between our device and the predicate devices.

Item	**Subject Device (K202009)**	**Predicate Devices (K102508)**	**Remark**
Trade Name	Probe Cover	Yu Long Sheng Disposable Thermometer Sheath	/
Model	JZ-KBT-001, JZ-KBT-002, JZ-KBT-005,JZ-KBT-007, JZ-KBT-008, JZ-KBT-009, JZ-KBT-010, JZ-KBT-015, JZ-KBT-025, JZ-KBT-026	YLS-01	/
Classifications Name & Citations	21 CFR 880.2910 Clinical electronic thermometer (FLL)	21 CFR 880.2910 Clinical electronic thermometer (FLL)	Same
Intended Use	Probe Cover is intended for use as a barrier that is used as an accessory to oral or axillary for digital thermometers. This probe cover is non-sterile and is intended for single patient use only.	YLS-01 disposable thermometer sheath is intended for use as a barrier that is used as an accessory to oral or rectal for digital thermometers. This thermometer sheath is non-sterile and is intended for single patient use only.	Different 1
Construction	PE film with upper and lower exterior protection paper.	EVA film with upper and lower exterior protection paper.	Different 2
Natural rubber latex	Do not contain natural rubber latex	Do not contain natural rubber latex	Same

Use type	For single use	For single use	Same
Size of single piece	125×30mm; 150×40mm; 125×40mm; 150×70mm; 235×50mm; 235×70mm; 235×35mm; 100×30mm;	94×26mm	Different 3
Package unit	100pcs in one packaging unit; 50pcs in one packaging unit;	50 pcs in one packaging unit	Different 4
Sterile Package	Non-sterile package	Non-sterile package	Same
Biocompatibility test	Biocompatibility test according to ISO 10993-5&ISO 10993-10	Biocompatibility test according to ISO 10993-5&ISO 10993-10	Same
Performance test	Performance test according to ASTM E 1104-98 &ASTM E 1112-00	Performance test according to ASTM E 1104-98 &ASTM E 1112-00	Same

Our device and the predicate device differ in the following areas.

(1) Intended use

The intended use of proposed device is to used as an an accessory to oral or axillary for digital thermometers. While the intended use of predicate device is used as an accessory to oral or rectal for digital thermometers. The different is just the body contact site. Biocompatibility test is conducted on the proposed device and the result is qualified. The biocompatibility is safe. At the same time the performance test of proposed device is conducted according to ASTM E 1104-98 &ASTM E 1112-00 and the result is qualified. The product is safe and effective.

So this difference does not affect the effectiveness and safety of our device.

(2) Construction

The construction of proposed device is PE film with upper and Lower exterior protection

paper. While the construction of predicate device is EVA film with upper and Lower exterior protection paper. The different is just the material of film. Biocompatibility test is conducted on the proposed device and the result is qualified. The biocompatibility is safe. At the same time the performance test of proposed device is conducted according to ASTM E 1104-98 &ASTM E 1112-00 and the result is qualified. The product is safe and effective.

So this difference does not affect the effectiveness and safety of our device.

(3) Size of single piece

The size of single piece of proposed device is varied size. While the size of single piece of predicate device is 94×26mm. Every size of propose device is conducted according to ASTM E 1104-98 &ASTM E 1112-00 and the result is qualified. All sizes of proposed device are safe and effective.

So this difference does not affect the effectiveness and safety of our device.

(4) Package unit

The package unit of proposed device is varied. Different model with varied pieces in packaging unit. While the predicate device is only one model and 50 pieces in one package unit. The package does not affect the clinical use of the device.

So this difference does not affect the effectiveness and safety of our device.

8. Non-Clinical Performance Data

Biocompatibility Tests

The Probe Cover has been evaluated in accordance with Part 10993 of the International Standard Organization (ISO). Standard tests administered include:

- 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.

Performance Tests

- ASTM E1104-98 (Reapproved 2016): Standard Specification for Clinical Thermometer Probe Covers and Sheaths
- ASTM E1112-00 (Reapproved 2011): Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature

Conclusion: The Probe Cover have demonstrated the product has similar intended use and similar technological characteristics as that of the predicate device. Performance testing showed it performs in a manner that is substantially equivalent to the legally marketed predicate device.

9. Substantial Equivalent Conclusions

Probe Cover has the similar intended use, similar technological characteristics as the predicate device. Moreover, non-clinical testing contained in this submission demonstrated that any difference in their technological characteristics does not raise any new issues of safety and effectiveness.

In conclusion, Probe Cover is substantial equivalent to the predicate device.