March 9, 2021

Dongguan Prestige Sporting Goods Co., Ltd
% Ms. Cassie Lee
Official Correspondent
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road
Huangpu District
Guangzhou, Guangdong 510000
China

Re: K201508
Trade/Device Name: Infrared Thermometer, Model STM-20
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: February 4, 2021
Received: February 9, 2021

Dear Ms. Cassie Lee:

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)*
K201508

Device Name
Infrared Thermometer (Model: STM-20)

Indications for Use *(Describe)*
Infrared Thermometer (model: STM-20) is a non-sterile, reusable, handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of people over one month old by detecting infrared heat from the forehead.

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 for K201508

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

1. Submitter's Information

510(k) Owner's Name: Dongguan Prestige Sporting Goods Co., Ltd

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Contact Person: Zhang, Zhao (General Manager)

Email: leon@solaxtech.com

Application Correspondent:

Contact Person: Cassie Lee

Guangzhou GLOMED Biological Technology Co., Ltd.

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Tel: +86 20 8266 2446

Email: regulatory@glomed-info.com

Date of the summary prepared: February 23, 2021

2. Subject Device Information

Trade Name: Infrared Thermometer (model: STM-20)

Common Name: Clinical electronic thermometer

Classification name: Thermometer, electronic, clinical

Review Panel: General Hospital

Product Code: FLL

Regulation Class: II

Regulation Number: 21 CFR 880.2910

3. Predicate Device Information

Sponsor: Intrinity Global Limited

Trade Name: Non Contact Infrared Forehead Thermometer(model:TVT-200, TVT-200 PLUS)

Classification Name: Clinical Electronic Thermometer

Common Name: Infrared Thermometer

510(K) Number: K170662

Review Panel: General Hospital

Product Code: FLL

Regulation Number: 880.2910

Regulation Class: II

4. Device Description

Infrared Thermometer (model: STM-20) is a hand-held, battery powered, non-contact infrared thermometer that coverts a user's forehead temperature, using the infrared energy emitted in the area around the user's forehead, to an oral equivalent temperature when placed within 1-3 cm from the subject's forehead with no contact. The Infrared Thermometer referenced body site is oral temperature. The laboratory accuracy of rated output temperature range 34°C~42°C (93.2°F to 107.6°F) is ±0.2°C (0.4°F). The rated extended output range is 32°C~33.9°C (89.6°F to 93.0°F), 42.1°C~43°C (107.8°F to 109.4°F) and the laboratory accuracy is ±0.2°C (0.4°F) as well. The device can be used in the hospital or at home.

It uses a thermopile sensor with integrated thermistor for the target reading and a thermistor mounted in the head of the thermometer for ambient temperature readings.

It composed by a measuring sensor, PCB, 3 buttons, a LCD and an enclosure. Press the measurement key to turn on the device. The screen of the device lights up. The LCD screen has the power symbol, measurement mode, temperature unit and measurement temperature. When measuring body temperature, users need to keep the measurement distance 1-3 cm from the subject's center of forehead with no contact. Press the measuring key, after 1 second with the sound of "beep", the measurement is completed and the temperature is displayed on the LCD screen. Without any operation, it will close automatically in 30±5 seconds.

User contacts components are the enclosure and keys. The materials of the components are ABS plastic and it no any color additives.

5. Intended Use / Indications for Use

Infrared Thermometer (model: STM-20) is a non-sterile, reusable, handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of people over one month old by detecting infrared heat from the forehead.

6. Comparison to predicate device

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Infrared Thermometer is substantially equivalent to the predicate device quoted above.

Elements of Comparison	**Subject Device**	**Predicate Device**	**Verdict**
Company	Dongguan Prestige Sporting Goods Co., Ltd	Intrinity Global Limited	--
Trade Name	Infrared Thermometer	Non Contact Infrared Forehead Thermometer	--
Classification Name	Clinical Electronic Thermometer	Clinical Electronic Thermometer	Same
510(k) Number	K201508	K170662	--
Product Code	FLL	FLL	Same
Intended Use / Indications for Use	Infrared Thermometer (model: STM-20) is a non-sterile, reusable, handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of people over one month old by detecting infrared heat from the forehead.	Non Contact Infrared Forehead Thermometer is a non-sterile, reusable, handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of all ranges of people by detecting infrared heat from the forehead.	Different Note 3
Display	LCD Digital Display	LCD Digital Display	Same
Measurement method	Infrared radiation detection	Infrared radiation detection	Same
Measurement mode	Forehead measure mode	Forehead measure mode	Same
Measuring range	32°C to 43°C (89.6°F to 109.4°F)	32° C to 43°C (89.6°F to 109.4°F)	Same
Display resolution	0.1°C/0.1°F	0.1°C/0.1°F	Same
C/F	YES	YES	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
switchable			
Measuring accuracy	±0.2°C (0.4°F)	±0.2°C (0.4°F)	Same
Measurement distance	1-3 cm	1 cm	Similar Note 1
Memory	None	16 sets.	Different Note 2
Power source	DC 3V	DC 3V	Same
Operating condition	5°C ~ 40°C; 15% ~ 85%RH	15°C~ 40°C (59°F~ 104°F); ≤95% RH	Different Note 2
Transport storage environment	-20°C ~ 55°C; ≤ 93%RH	Not public	Different Note 2
Patient contact materials	ABS	ABS with colorants (pink, grey, orange and purple), Glass and Metal	Same
Cleaning/ disinfection	The thermometer casing and the measuring probe should be cleaned and disinfected by 70% alcohol.	The thermometer casing and the measuring probe should be cleaned and disinfected by 70% alcohol.	Same
Electric Safety and EMC	IEC 60601-1 lEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-56	IEC 60601-1 lEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-56	Same

Comparison in Detail(s):

Note 1:

The “Measurement distance” of subject device is similar with predicate device, both of them meet the requirement of safety and essential performance standard ISO 80601-2-56. The differences between the predicate device and subject device does not affect the safety and effectiveness of the subject device.

Note 2:

The “Memory”, “Operating condition” and “Transport storage environment” of subject device is different with predicate device. There is no memory feature in the subject device and memory

feature is not an essential requirement of IR thermometers. The operating condition and transport storage environment met the requirements of standard ISO 80601-2-56. The performance test shows the subject device complies with performance standard.
The differences between the predicate device and subject device does not affect the safety and effectiveness of the subject device.

Note 3:

The patient population of the subject device is a subset of the predicate device. The subject device met the requirements of the standards ISO 80601-2-56 and ASTM E1965-98. Based on the performance evaluation, the differences between the predicate device and subject device does not affect the safety and effectiveness of the subject device.

7. Summary of Non-Clinical Testing

7.1 Non-clinical testing was conducted to verify that the subject device met all design specifications, demonstrated safety based on current industry standards, and to demonstrate substantial equivalence to the predicate. The following tests were performed:

Infrared Thermometer has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD), IEC 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- Electromagnetic compatibility test according to IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- Software verification and validation test according to the requirements of the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)"

- ISO 80601-2-56 Second edition 2017-03, Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)].
- ASTM E1965-98 (2016): Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

7.2 Discussion of Clinical Tests Performed

The clinical performance test protocol and data analysis is conducted as the requirement of ASTM E1965-98 (2016). The test report showed the clinical performance of the subject device complied with ASTM E1965-98 (2016).

Clinical tests were conducted on the subject device Model STM-20. The clinical tests evaluated 240 of subjects. The proposed thermometer was evaluated in four groups A1 - one month up to three month, A2 - three months to one year; B1 -older than one years and younger than five years; and C - older than five years old. The clinical performance test protocol and data analysis were conducted in accordance with the ASTM E1965-98 (2016). The test report showed the clinical performance of the subject device complied with ASTM E1965-98 (2016).

8. Final Conclusion：

Based on the performance testing, comparison and analysis, the subject device Infrared Thermometer (model: STM-20) is substantially equivalent to the predicate device.