September 24, 2018

K-jump Health Co., Ltd.
JM Lin
Regulatory Affairs Representative
No. 56, Wu Kung 5th Road, New Taipei Industrial Park
New Taipei City, 24890
Taiwan

Re: K180714
  Trade/Device Name: Probe Covers for Thermometers
  Regulation Number: 21 CFR 880.2910
  Regulation Name: Clinical Electronic Thermometer
  Regulatory Class: Class II
  Product Code: FLL
  Dated: August 22, 2018
  Received: August 24, 2018

Dear JM Lin:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting 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

The Probe Covers for Thermometers are intended for use as barriers between thermometers and oral cavities or users' rectum. The subject devices are used as accessories for digital thermometers and intended for single use only.

Type of Use (Select one or both, as applicable)

- [ ] Prescription Use (Part 21 CFR 801 Subpart D)
- [x] 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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"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."
This is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter information

Company Name: K-jump Health Co., Ltd.
Address: No. 56, Wu Kung 5th Rd. New Taipei Industrial Park, New Taipei City 24890, Taiwan
Contact person: JM Lin, Regulatory Affairs Representative
Phone: +886-2-2299-1378 ext. 237
Fax: +886-2-2299-1385
Email: jm@kjump.com.tw
Prepared date: March 13, 2018

2. Name of Device

Trade Name: Probe Covers for Thermometers
Common/Usual Name: Disposable Thermometer Covers and Sheaths
Regulation Number: 21 CFR 880.2910
Classification Name: Clinical electronic thermometer
Regulatory Class: II
Product Code: FLL

3. Predicate Device

<table>
<thead>
<tr>
<th>Device Name</th>
<th>510(k) Number</th>
<th>Decision Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yu Long Sheng Disposable Thermometer Sheath (YU LONG SHENG TECHNOLOGY CO., LTD.)</td>
<td>K102508</td>
<td>01/10/2011</td>
</tr>
</tbody>
</table>

This predicate has not been subject to a design-related recall.
4. Device Description

The Probe Covers for Thermometers, which made of PE and EVA, are used for thermometers as barriers during oral or rectal temperature measurements. The Probe Covers are suitable for varied thermometers and non-sterilized packaging.

5. Indications for Use

The Probe Covers for Thermometers are intended for use as barriers between thermometers and oral cavities or users' rectum. The subject devices are used as accessories for digital thermometers and intended for single use only.

6. Comparison of technological characteristics with Predicate Device

The subject device is substantially equivalent to the predicate device, K102508, the disposable thermometer probe sheath. The comparison of their characteristics is summarized in the table below.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>K-JUMP HEALTH CO., LTD. K180714</th>
<th>YU LONG SHENG TECHNOLOGY CO., LTD K102508</th>
<th>Indicate difference or similarity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device name</td>
<td>Probe Covers for Thermometers</td>
<td>Yu Long Sheng Disposable Thermometer Sheath /Model YLS-01</td>
<td>difference</td>
</tr>
<tr>
<td>Indications for Use.</td>
<td>The Probe Covers for Thermometers are intended for use as barriers between thermometers and oral cavities or users' rectum. The subject devices are used as accessories to oral or rectal for digital thermometers. This sheath is non-sterile and is intended for single patient use</td>
<td>YLS-01 is intended for use as a barrier that is used as an accessory to oral or rectal for digital thermometers. This sheath is non-sterile and is intended for single patient use</td>
<td>similarity</td>
</tr>
</tbody>
</table>
### 510(k) Summary

#### Discussion of Main Differences:

Both the subject device and predicate device have the similar intended use, same materials and structures. The only minor difference are the dimension and appearance. The subject device is substantial equivalent to the predicate device according to both of them are complied with the same performance standards.

#### 7. Performance Summary

The performance of the Probe Covers for Thermometers is verified and validated to comply with following recognized standards and does not raise any performance issues.

1. **Performance**
   - ASTM E1104-98 (Reapproved 2016) Standard Specification for Clinical Probe Covers and Sheaths
The subject device complies with ASTM E1104-98 requirements including general requirements, toxicity test, leakage test, compatibility test and storage environment test.

2. Biocompatibility:
   ISO 10993-5 Third Edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity and
   ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

   The subject device complies with applicable biocompatibility requirements and the device meets the endpoints for cytotoxicity, sensitization & irritation-negligible.

8. Conclusions

The Probe Covers for Thermometers have the similar intended use, materials and technological characteristics with the predicate device. Moreover, both devices comply with same performance standards. All information described above can demonstrate the subject device is substantial equivalent to the predicate device.