May 9, 2022

Promisemed Hangzhou Meditech Co., Ltd.
Zearou Yang
Regulatory Affairs Manager
No. 1388 Cangxing Street, Cangqian Community,Yuhang District
Hangzhou City, Zhejiang 311121
China

Re: K213683
Trade/Device Name: Promisemed Fine Biopsy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW

Dear Zearou Yang:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 22, 2022. Specifically, FDA is updating this SE Letter with corrected Indications for Use as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Long Chen, Ph.D., OHT4: Office of Surgical and Infection Control Devices, 301-796-6389, long.chen@fda.hhs.gov.

Sincerely,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2022.05.09 14:58:54 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

April 22, 2022

Promisemed Hangzhou Meditech Co., Ltd.
Mr. Zearou Yang
Regulatory Affairs Manager
No. 1388 Cangxing Street, Cangqian Community,Yuhang District
Hangzhou City, Zhejiang 311121
China

Re: K213683
Trade/Device Name: Promisemed Fine Biopsy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: Februry 11, 2022
Received: February 24, 2022

Dear Mr.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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2022.04.22 14:15:46 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K213683

Device Name
Promisemed Fine Biopsy Needle

Indications for Use *(Describe)*
It is to be used for taking cytological and histological biopsies of soft tissue.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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."

510(k) Summary

1. Date Prepared

April 25, 2022.

2. Submitter's Information

Name of Sponsor:

Promisemed Hangzhou Meditech Co., Ltd.

Address:

No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, China

Contact Name: Zearou Yang

Telephone No.:

+86 571 88772985

Fax No.:

+86 571 88772985

Email Address:

zearou.yang@promisemed.ca

3. Trade Name, Common Name, Classification

Trade/Product Name: Promisemed Fine Biopsy Needle

Common Name: Fine Biopsy Needle

Classification name: Instrument, biopsy

Regulation Number: 876.1075

Device Class: Class II

Product Code: KNW

4. Identification of Predicate Device

K970872: Pan® Aspirating Needle (Chiba)

5. Description of the Device

The device is a hand-operated, non-electronic, with Chiba tip for tissue pathological examination/testing.

- Trasparent Luer Lock connector.
- Sharpened cannula for a safe and painless insertion and penetration.

- External echogenic treatment for a correct positioning under ultrasound guidance.
- Centimeter markings and sliding stopper.
- Sterilized by ETO, shelf life 5 years.

It's a relatively invasive procedure and is performed by radiologist under guidance of imaging techniques such as ultrasound, X-ray.

This is a single-use device.

Not intended for use in bone.

6. Indication

It is to be used for taking cytological and histological biopsies of soft tissue.

7. Similarities and Differences of the Proposed Devices to the Predicate Devices

Promisemed Fine Biopsy Needle is substantially equivalent to the predicate device, Pan Aspirating Needle (Chiba), K970872 in that these devices have same intended use and technological characteristics. The basic technological and operating principles are the same for both devices. Both the subject and predicate devices are disposable, sterile, single patient use devices. The differences between the subject device and predicate device do not affect the basic design principle, usage of the subject device.

A detailed comparison to the predicate is provided in Table 1.

Items	Subject Device	Predicate Device (K970872)	Comments
Trade Name	Promisemed Fine Biopsy Needle	Pan® Aspirating Needle (Chiba)	
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd	Gallini International, Inc.	
Device Class	Class II	Class II	Same
Product Code	KNW	KNW	Same
Regulation number	876.1075	876.1075	Same
Regulation Name	Instrument, biopsy	Instrument, biopsy	Same
Intended Use/ Indications for Use	It is to be used for taking cytological and histological biopsies of soft tissue.	It is to be used for taking cytological and histological biopsies of soft tissue.	Same
Operating Principle	It's a relatively invasive procedure and is performed by radiologist under guidance of imaging techniques such as ultrasound, X-ray.	It's a relatively invasive procedure and is performed by radiologist under guidance of imaging techniques such as ultrasound, X-ray.	Same
Materials	- Needle: Stainless Steel (X5CrNi18-10); - Needle base: Acrylonitrile Butadiene Styrene (ABS);	- Needle: Stainless Steel (X5CrNi18-10); - Needle base: Acrylonitrile Butadiene Styrene (ABS);	Same

<table>
<tr><td></td><td>- Depth stop: Thermoplastic Elastomer (TPE);</td><td>- Depth stop: Thermoplastic Elastomer (TPE);</td><td></td></tr>
<tr><td>Reuse durability</td><td>Single Use</td><td>Single Use</td><td>Same</td></tr>
<tr><td colspan="4">Performance:</td></tr>
<tr><td>Echogenic</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td>Connector transparency</td><td>Transparent/lock</td><td>Transparent/lock</td><td>Same</td></tr>
<tr><td>Needle Gauge</td><td>16G, 18G, 19G, 20G, 21G, 22G, 23G</td><td>18G, 20G, 21G, 22G, 23G, 25G</td><td>Subject device has two gauge sizes (16G, 19G) more than predicate device.
The 16G OD of needle tube which providing more samples volume and reduce operation time during clinical procedure, therefore, introduce any new concerns for safety or efficacy.</td></tr>
<tr><td>Needle Length</td><td>90mm, 100mm, 150mm, 200mm</td><td>50mm, 80mm, 90mm, 150mm, 200mm</td><td>Different
Subject device has less needle length than predicate device.</td></tr>
<tr><td>Inner needle hub color</td><td>Per ISO 6009:
White/16G, Pink/18G, Cream/19G, Yellow/20G, Light green/21G, Black/22G, Light blue/23G.</td><td>Per ISO 6009:
Pink/18G, Yellow/20G, Light green/21G, Black/22G, Light blue/23G, Orange/25G</td><td>Each color is in accordance with ISO 6009.</td></tr>
<tr><td>Needle tube tip type</td><td>Chiba</td><td>Chiba</td><td>Same</td></tr>
<tr><td>Bond between outer needle tube and hub</td><td>according to the nominal OD of the outer needle, the outer needle and hub shall not break when pull the needle with the axial static force specified in the below table for 10s.<table><tr><td>OD</td><td>Force /N</td></tr><tr><td>23G</td><td>34</td></tr></table></td><td>according to the nominal OD of the outer needle, the outer needle and hub shall not break when pull the needle with the axial static force specified in the below table for 10s.<table><tr><td>OD</td><td>Force /N</td></tr><tr><td>23G</td><td>34</td></tr></table></td><td>Same</td></tr>
<tr><td>Bond between inner needle tube and hub</td><td>The inner needle and hub shall not break when pull the needle with the axial static force specified in the below table for 10s.<table><tr><td>OD</td><td>Force /N</td></tr><tr><td>23G</td><td>10</td></tr></table></td><td>The inner needle and hub shall not break when pull the needle with the axial static force specified in the below table for 10s.<table><tr><td>OD</td><td>Force /N</td></tr><tr><td>23G</td><td>10</td></tr></table></td><td>Same</td></tr>
<tr><td>Needle tube performance</td><td>Per ISO 9626:
- Stiffness;</td><td>Per ISO 9626:
- Stiffness;</td><td>Same</td></tr>
</table>

	- Resistance to breakage; - Resistance to corrosion;	- Resistance to breakage; - Resistance to corrosion;	
Scale identification	The scale line shall form a ring on the outside of the needle tube and be clearly discernible. The distance from the tip of the inner needle to the front edge of the first scale line shall be 10mm±1.5mm as well as any two adjacent tick marks	The scale line shall form a ring on the outside of the needle tube and be clearly discernible. The distance from the tip of the inner needle to the front edge of the first scale line shall be 10mm±1.5mm as well as any two adjacent tick marks	Same
Lucer lock Connector performance	Per ISO 80369-7: - Positive pressure liquid leakage; - Sub-atmospheric pressure air leakage; - Stress cracking; - Resistance to separation from axial load; - Resistance to separation from unscrewing; - Resistance to overriding;	Per ISO 80369-7: - Positive pressure liquid leakage; - Sub-atmospheric pressure air leakage; - Stress cracking; - Resistance to separation from axial load; - Resistance to separation from unscrewing; - Resistance to overriding;	Same
Sterilizatio n method	EO Sterilization	EO Sterilization	Same
Shelf life	5 years	5 years	Same
Biocompatibility	Complied with ISO10993 series standards, and the following tests are performed - Cytotoxicity: No cytotoxicity; - Skin Irritation: No evidence of skin irritation; - Skin Sensitization: No evidence of sensitization; - Acute Systemic Toxicity: No systemic toxicity; - Pyrogen: Non pyrogenic;	Complied with ISO10993 series standards, and the following tests are performed - Cytotoxicity: No cytotoxicity; - Skin Irritation: No evidence of skin irritation; - Skin Sensitization: No evidence of sensitization; - Acute Systemic Toxicity: No systemic toxicity; - Pyrogen: Non pyrogenic;	Same

8. Performance Testing Summary

The bench testing performed verifies that the performance of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include:

- Appearance;
- Cleanliness;
- Color code;
- Dimensions;
- Needle point;
- Patency of lumen;
- Tip structure;

- Bond between outer needle tube and hub;
- Bond between inner needle tube and hub;
- Sheath;
- Stiffness;
- Resistance to breakage;
- Resistance to corrosion;
- Scale identification;
- Positive pressure liquid leakage;
- Sub-atmospheric pressure air leakage;
- Stress cracking;
- Resistance to separation from axial load;
- Resistance to separation from unscrewing;
- Resistance to overriding;

The performance test results are indicated that performance of Fine Biopsy Needles meet the specific requirements. We concluded the proposed devices are substantially equivalent to the identified predicate devices in general appearance, dimension, needle tube performance, color, scale and connector.

9. Conclusion

Based on the information provided within this 510(k) submission, proposed subject device is substantially equivalent to the predicate device and is as safe, as effective and performs as well as the legally marketed predicate device.