August 12, 2021

Promisemed Hangzhou Meditech Co., Ltd.
% Ms. Wei-Shan Hsu
Regulatory Manager
Vee Care (Asia) Limited
17F Chung Pont Commercial Building, 300 Hennessy Road
Hong Kong, China

Re: K210946
Trade/Device Name: Promisemed Automatic Biopsy Needles,
Promisemed Co-Axial Biopsy Devices,
Promisemed Semi-Automatic Biopsy Needles

Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: May 5, 2021
Received: June 21, 2021

Dear Ms. Wei-Shan Hsu:

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 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)*
K210946

Device Name
Promisemed Automatic Biopsy Needles
Promisemed Co-Axial Biopsy Devices
Promisemed Semi-automatic Biopsy Needles

Indications for Use *(Describe)*

Automatic Biopsy Needles are intended in obtaining biopsy samples from soft tissues such as liver, kidney, prostate, breast, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

Co-Axial Biopsy Device is mainly used to guide the insertion of biopsy needle into the soft tissue under imaging control (ultrasound, X-ray, CT, etc.). It is not intended for use in bone.

Semi-automatic Biopsy Needles are intended in obtaining biopsy samples from soft tissues such as liver, kidney, prostate, breast, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

When used for breast biopsy, the product is for diagnosis only. The extent of histological abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histological abnormality; e.g., malignancy. When sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal of using standard surgical procedures.

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.

510(k) Summary

1 Date Prepared

Aug 5th , 2021

2 Submitter's Information

Submission Sponsor:

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Contact Name: Ms. Wei-Shan Hsu, Regulatory manager

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3 Trade Name, Common Name, Classification

Trade/Product Name: Promisemed Automatic Biopsy Needles
Promisemed Co-Axial Biopsy Devices
Promisemed Semi-automatic Biopsy Needles

Common Name: Biopsy Devices and Accessories

Classification name: Gastroenterology-urology biopsy instrument

Regulation Number: 21 CFR 876.1075

Device Class: Class II

Product Code: KNW, FCG

4 Identification of Predicate Devices

K192101: MEDONE ULTRA Soft tissue programmable automatic disposable biopsy system

K181803: VELOX 2 Biopsy Needle

K160423: Perineologic Access Needle

5 Description of the Device

Promisemed Automatic Biopsy Needles, Semi-automatic Biopsy Needles and Co-axial Biopsy Devices are hand-operated, non-electronic, surgical instruments.

Promisemed Automatic Biopsy Needles is designed for the automatic extraction of a specimen from soft tissues, while causing minimal surrounding tissue damage, for tissue pathological examination/ testing. Push the outer needle backward to expose the sampling slot of the inner needle by compression spring, then the spring's resilience realizes the movement of the outer needle and the excitation function.

Promisemed Semi-automatic Biopsy Needles is designed for the extraction of a specimen from soft tissues, while causing minimal surrounding tissue damage, for tissue pathological examination/testing. The semi-automated biopsy needle requires manual advancement of the inner needle to expose the specimen notch. With pressure on its plunger, a spring action rapidly advances the outer needle (cutting cannula) over the specimen notch of the inner needle.

Promisemed Co-Axial Biopsy Device is used with biopsy needles to guide the insertion of biopsy needle into the soft tissue under imaging control (ultrasound, X-ray, CT, etc.). It is supplied with trocar tip stylet with or without blunt tip stylet.

Promisemed biopsy device and accessories are sterile with a Sterility Assurance Level (SAL) of 10^{-6}, non-pyrogenic and single-use devices.

The ultrasound, X-ray, CT and other equipments are used to guide the puncture and sampling. These products can’t be used under MRI.

6 Indication

Automatic biopsy needles are intended in obtaining biopsy samples from soft tissues such as liver, kidney, prostate, breast, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

Co-Axial Biopsy Device is mainly used to guide the insertion of biopsy needle into the soft tissue under imaging control (ultrasound, X-ray, CT, etc.). It is not intended for use in bone.

Semi-automatic Biopsy Needles are intended in obtaining biopsy samples from soft tissues such as liver, kidney, prostate, breast, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

When used for breast biopsy, the product is for diagnosis only. The extent of histological abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histological abnormality; e.g., malignancy. When sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal of using standard surgical procedures.

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

The Promisemed Biopsy Devices and Accessories are substantially equivalent to the predicate devices in terms of intended use and technological characteristics. The differences above between the subject devices and predicate devices do not affect the basic design principle, usage, effectiveness and safety of the subject device. Equivalence has been identified as follows:

Subject device	Predicate Device
Promisemed Automatic Biopsy Needle	K192101 MEDONE ULTRA Soft tissue programmable automatic disposable biopsy system
Promisemed Semi-automatic Biopsy Needle	K181803 VELOX 2 Biopsy Needle
Promisemed Co-Axial Biopsy device	K160423 Perineologic Access Needle

Table 1. Comparison of the Promisemed Automatic Biopsy Needle to the predicate device.

	Subject Device	Predicate Device (K192101)	Comments
Trade Name	Promisemed Automatic Biopsy Needle	Medax MEDONE ULTRA	
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd	MEDAX S.R.L. UNIPERSONALE	
Device Class	Class II	Class II	Same
Product Code	KNW	KNW	Same
Regulation number	876.1075	876.1075	Same
Regulation Name	Gastroenterology-Urology Biopsy Instrument	Gastroenterology-Urology Biopsy Instrument	Same
Device Description	Disposable programmable automatic spring-loaded guillotine style biopsy system for histological biopsy on soft tissue.	Disposable programmable automatic spring-loaded guillotine style biopsy system for histological biopsy on soft tissue.	Same
Intended Use/ Indications for Use	Automatic biopsy needles are intended in obtaining biopsy samples from soft tissues such as liver, kidney, prostate, breast, lymph nodes and various soft tissue tumors. It is not intended for use in bone.	Medax MEDONE ULTRA intended for use in obtaining core biopsy samples from soft tissue such as kidney, liver, prostrate, spleen, lymph nodes, and various soft tissue masses. Not intended for use in bone.	Same
Target Population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities	Same
Mechanics of Operation	Single hand automatic activation	Single hand automatic activation	Same
Gauge	12G-20G	14G-20G	Different The subject device has smaller gauge than predicate device
Needle Length	90mm-200mm	60 mm to 200 mm	Different The range of needle length in

			subject device is within that of predicate device.
Patient/Tissue Contact Material	Inner needle and outer needle are made out of 304 stainless steel (X5CrNi18-10). Only Stainless steel is in direct surgical contact with all soft tissues of the patient.	Cannula and mandrel are made out of AISI 304 stainless steel. Only Stainless steel is in direct surgical contact with all soft tissues of the patient.	Same
Performance	Complied with ISO 9626	Complied with ISO 9626	Same
Sterilization	EO Sterilization	EO Sterilization	Same
Single use	Yes	Yes	Same
Biocompatibility	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts	Same

Table 2: Comparison of the Promisemed Semi-automatic Biopsy Needle to the predicate device.

	Subject Device	Predicate Device (K181803)	Comments
Trade Name	Promisemed Semi-automatic Biopsy Needle	MEDEXTRA	
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd	MEDAX S.R.L. UNIPERSONALE	
Device Class	Class II	Class II	Same
Product Code	KNW	KNW	Same
Regulation number	876.1075	876.1075	Same
Regulation Name	Gastroenterology-Urology Biopsy Instrument	Gastroenterology-Urology Biopsy Instrument	Same
Device Description	Disposable semi-automatic spring loaded guillotine style biopsy system with adjustable penetration depth for histological biopsy on soft tissue.	Disposable semi-automatic spring loaded guillotine style biopsy system with adjustable penetration depth for histological biopsy on soft tissue.	Same
Intended Use/ Indications for Use	Semi-automatic biopsy needles are intended in obtaining biopsy samples from soft	The device is intended for use in obtaining biopsies from soft tissues such as liver,	Same

	tissues such as liver, kidney, prostate, breast, lymph nodes and various soft tissue tumors. It is not intended for use in bone.	kidney, prostate, breast, spleen, lymph nodes and various soft tissue masses. It is not intended for use in bone biopsy.	
Target Population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities	Same
Mechanics of Operation	Single hand automatic activation	Single hand automatic activation	Same
Gauge	14G-20G	14G-20G	Same
Needle Length	90mm-220mm	80 mm to 300 mm	Different The range of needle length in subject device is within that of predicate device.
Patient/Tissue Contact Material	Inner needle and outer needle are made out of 304 stainless stee (X5CrNi18-10). Only Stainless steel is in direct surgical contact with all soft tissues of the patient.	Cannula and mandrel are made out of AISI 304 stainless steel. Only Stainless steel is in direct surgical contact with all soft tissues of the patient.	Same
Sterilization	EO Sterilization	EO Sterilization	Same
Single use	Yes	Yes	Same
Biocompatibility	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts	Same

Table 3: Comparison of the Promisemed Co-Axial Biopsy Device to the predicate device.

	Subject Device	Predicate Device (K160423)	Comments
Trade Name	Promisemed Semi-automatic Biopsy Needle	Perineologic Access Needle	
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd	Corbin Clinical Resources, LLC	
Device Class	Class II	Class II	Same

Product Code	FCG	FCG	Same
Regulation number	876.1075	876.1075	Same
Regulation Name	Gastroenterology-Urology Biopsy Instrument	Gastroenterology-Urology Biopsy Instrument	Same
Intended Use/ Indications for Use	Co-axial biopsy device is mainly used to guide the insertion of biopsy needle into the soft tissue under imaging control (ultrasound, X-ray, CT, etc.). It is not intended for use in bone.	The Perineologic Access Needle is intended for use as a guiding needle in obtaining core biopsy samples from soft tissue and tumors of such organs as liver, kidney, spleen, lymph nodes, prostate, lung and various soft tissue lesions.	Same
Target Population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities	Same
Gauge	11G-19G	14G-20G	Different The subject device has smaller gauge than predicate device.
Needle Length	60mm-190mm	70 mm to 200 mm	Different The subject device has shorter needle length than predicate device.
Device Type	Trocar tip stylet with/ without blunt tip stylet	Trocar tip stylet	Different Subject device has blunt tip stylet as an option to minimize the risk of unintentional damage to target tissue.
Visualization Technique	Conventional imaging guidance equipment excluding MRI	Conventional imaging guidance equipment excluding MRI	Same
Needle Material	Stainless steel	Stainless steel	Same
Sterilization	EO Sterilization	EO Sterilization	Same
Single use	Yes	Yes	Same

Biocompatibility	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts	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. Other tests include:

- ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
- Biocompatibility
  a. ISO 10993-1:2009 – Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process
  b. ISO 10993-5:2009 – Biological Evaluation of Medical Devices -- Part 5: Tests for in Vitro Cytotoxicity
  c. ISO 10993-7:2008, Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
  d. ISO 10993-10:2010 – Biological Evaluation of Medical Devices -- Part 10: Tests for Irritation and Skin Sensitization
  e. ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity-Acute systemic toxicity
  f. USP42-NF37<151> Pyrogen Test

9 Conclusion

Based on the information provided within this 510(k) submission, proposed Promisemed Biopsy Devices and Accessories are substantially equivalent to the predicate devices and are as safe, as effective and perform as well as the legally marketed predicate devices.