May 12, 2026

Promisemed Hangzhou Meditech Co., Ltd.
Zearou Yang
Regulatory affairs manager
#1388 Cangxing St., Cangqian Community, Yuhang District
Hangzhou City, 311121
China

Re: K261196
Trade/Device Name: Promisemed VeriEcto Automatic Biopsy Needles
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: April 11, 2026
Received: April 13, 2026

Dear Zearou 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JESSICA CARR -S

Jessica Carr, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261196

Please provide the device trade name(s).

Promisemed VeriEcto Automatic Biopsy Needles

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

Promisemed Hangzhou Meditech Co., Ltd.
No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, P. R. China.

K261196-510(k) Summary

Date prepared: 2026-05-12

1. Manufacturer *[21 CFR 807.92 (a) (1)]*	
Name	Promisemed Hangzhou Meditech Co., Ltd.
Address	No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, China.
Contact Person	Zearou Yang
Phone	+86 571 88772985
Email	zearou.yang@promisemed.ca
2. Device *[21 CFR 807.92 (a) (2)]*	
Name	Promisemed VeriEcto Automatic Biopsy Needles
Common Name	Automatic Biopsy Needles
Classification Name	Gastroenterology-urology biopsy instrument
Regulation Number	21 CFR 876.1075
Class	Class II
Product Code	KNW, FCG
3. Legally Marketed Predicate Device *[21 CFR 807.92 (a) (3)]*	
Predicate Name	Promisemed Automatic Biopsy Needles
510(k) Number	K210946
Product Code	KNW, FCG
Reference Devices	No reference devices were used in this submission.

4. Device Description *[21 CFR 807.92 (a) (4)]*

Promisemed VeriEcto Automatic Biopsy Needles are hand-operated, non-electronic, surgical instruments. Promisemed VeriEcto Automatic Biopsy Needle 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.

It is a sterile with a Sterility Assurance Level (SAL) of 10^{-6}, non-pyrogenic and single-use device.

The ultrasound, X-ray, CT and other equipment are used to guide the puncture and sampling. This product can't be used under MRI.

5. Indication for use *[21 CFR 807.92 (a) (5)]*

The 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.

6. Comparison of Technological Characteristic *[21 CFR 807.92 (a) (6)]*

The Promisemed VeriEcto Automatic Biopsy Needle is substantially equivalent to the predicate device, K210946. Both devices have the same intended use. 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.

While certain technological differences exist between the subject and predicate devices, these differences do not raise different questions of safety and effectiveness and do not affect the fundamental design principles or safe usage of the device.

Item of description	**Predicate device** (K210946)	**Subject device** (K261196)	**Similar/ Differences**	**Safety / Effectiveness Statement**
Common name	Promisemed Automatic Biopsy Needles	Promisemed VeriEcto Automatic Biopsy Needles	N/A	/
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd.	Promisemed Hangzhou Meditech Co., Ltd.	Same	All produced by the same manufacturer.
Device class	Class II	Class II	Same	No new concerns.
Product Code	KNW, FCG	KNW, FCG	Same	No new concerns.
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.	The 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.	Same	No new concerns. More details about warning was added for safely usage.
Target population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities	Same	No new concerns.
Anatomical site	Soft tissues such as liver, kidney, prostate, breast, lymph nodes and various soft tissue tumors	Soft tissues such as liver, kidney, prostate, breast, lymph nodes and various soft tissue tumors	Same	No new concerns.
Where used	Professional Healthcare Facility	Professional Healthcare Facility	Same	No new concerns.
Human factors	Healthcare professional users	Healthcare professional users	Same	No new concerns.
Design	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	No new concerns. The fundamental technology and operation remain the same.
Structure	The disposable automatic biopsy needle is composed of biopsy needle and coaxial needle (optional). The device is composed of the inner needle, outer needle, mechanical power unit and sheath. The Co-Axial Biopsy Device is composed of the inner needle, outer needle, sheath, casing seat, base and screw cap for the models with the Co-Axial Biopsy Device.	The disposable automatic biopsy needle is composed of biopsy needle and coaxial needle (optional). The device is composed of the inner needle, outer needle, mechanical power unit and sheath. The Co-Axial Biopsy Device is composed of the inner needle, outer needle, sheath, casing seat, base and screw cap for the models with the Co-Axial Biopsy Device.	Similar	No new concerns. The fundamental technology and operation remain the same..
Materials (tissue-contacting)	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	<table><tr><th>Component</th><th>Material (ISO number)</th><th>Contact methods</th></tr><tr><td>Inner needle (Biopsy Needle)</td><td>Stainless steel (X12CrNi 17-7)</td><td>Direct contact Internal tissue</td></tr><tr><td>Outer needle (Biopsy Needle, *Co-axial needle*)</td><td>Stainless steel (X5CrNi1 8-10)</td><td>Externally communica ting, direct contact tissue.</td></tr></table>	Difference	Subject device inner needle of X12CrNi17-7 is contacting the tissue with Less than one hour. It does not introduce new risks through biocompatibility testing.

		Inner needle (*Co-axial needle*) / Stainless steel (X5CrNi18-10) / Externally communicating, direct contact tissue.		
Needle size (Biopsy Needle)	12G- 20G	12G, 14G, 16G, 18G, 20G	Same	No new concerns.
Needle length (Biopsy Needle)	90mm- 200mm.	90mm, 100mm, 130mm, 150mm, 160mm, 200mm, 220mm, 250mm	Difference	220mm and 250mm were added. Broader needle length for more selection during clinical procedure. Difference of needle length does not introduce new risks as the fundamental technology and operation remain the same.
Needle size (*Co-axial needle*)	11G-19G.	11G, 13G, 15G, 17G, 19G.	Same	No new concerns.
Needle length (*Co-axial needle*)	60mm-190mm.	60mm, 70mm, 100mm, 120mm, 130mm, 170mm, 190mm, 220mm.	Difference	220mm was added. Broader needle length for more selection during clinical procedure. Difference of needle length does not introduce new risks as the fundamental technology and operation remain the same.
Sterilization method	EO sterilization	EO sterilization	Same	No new concerns.
Sterility	SAL of 10^{-6}	SAL of 10^{-6}	Same	No new concerns.
Single use	Yes	Yes	Same	No new concerns.
Biocompatibility	Biocompatibility established	Biocompatibility established	Same	No new concerns.
Standards met	- ISO 9626:2016; - ISO 10993 series;	- ISO 9626:2016; - ISO 10993 series;	Same	No new concerns.
Compatibility with the environment and other devices	The introduction of the needle into the body should be carried out under imaging guidance (ultrasound, X-Ray, CT, etc.)	The introduction of the needle into the body should be carried out under imaging guidance (ultrasound, X-Ray, CT, etc.)	Same	No new concerns.
Energy used and/or delivered	Not applicable	Not applicable	/	/
Electrical safety	Not applicable	Not applicable	/	/
Mechanical safety	Not applicable	Not applicable	/	/
Chemical safety	Not applicable	Not applicable	/	/
Thermal safety	Not applicable	Not applicable	/	/
Radiation safety	Not applicable	Not applicable	/	/

The following changes were identified between the subject and predicate devices:

- Adding of needle lengths: The addition of new needle length expands options and new type without altering the device's safety or effectiveness when compared to the predicate device.
- Difference of inner needle material: biocompatibility of subject device material has been tested in accordance with ISO 10993 series that indicated is safely.

The subject device has the same intended use and technological characteristics as the predicate device. 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. As evidenced by comparison table above, the subject device is substantially equivalent to the predicate device.

7. Nonclinical test *[21 CFR 807.92 (b) (1)]*

Performance testing confirms that the output meets the design inputs and specifications. Internal verification and validation testing confirms that product specifications are met, which support the intended use and technological characteristics as compared to the predicate devices. The information supports the substantial equivalence to the referenced predicate device:

- Cleanliness;
- Size of outer needle;
- Needle points;
- Puncture force of needle point;
- Coordination of biopsy needle;
- Mechanical power unit;
- Bond between outer needle and upper slider;
- Bond between Inner needle and lower slider;
- Sheath;
- Resistance to breakage;
- Resistance to corrosion;
- Scale identification;
- Sampling type;

The subject device is meeting all the requirements for overall design and performance.

8. Clinical test *[21 CFR 807.92 (b) (2)]*

No clinical testing was conducted for this submission.

9. Conclusion *[21 CFR 807.92 (b) (3)]*

Based on the nonclinical performance testing described above, the Promisemed VeriEcto Automatic Biopsy Needle (subject device) has been demonstrated to be substantially equivalent to the predicate device (K210946). The subject device has the same intended use as the predicate device. While certain technological differences exist (needle length and material), these differences do not raise different questions of safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate device and is appropriate for clearance under the 510(k) pathway.