Suzhou Leapmed Healthcare Corporation
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801, No.161, East Lujiazui Rd., Pudong
Shanghai, Shanghai 200120
China

July 6, 2022

Re: K212820
Trade/Device Name: Disposable Semi Automatic Biopsy Instrument
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: FCG
Dated: May 26, 2022
Received: June 6, 2022

Dear Boyle Wang:

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

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)*
K212820

Device Name
Disposable Semi Automatic Biopsy Instrument

Indications for Use *(Describe)*
The Disposable Semi Automatic Biopsy Instrument is intended for obtaining percutaneous or surgical histological core samples from soft tissues such as breast, kidney, liver, lung and various soft tissue masses. The device is not intended for use in bone.
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 the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal 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.

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510(k) Summary

K212820

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

1.0 Submitter's Information

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Contact: Yu Zhu

Designated Submission Correspondent

Contact: Mr. Boyle Wang
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Tel: +86-21-50313932
Email: Info@truthful.com.cn

Date submitted: Jul.4, 2022

2.0 Device Information

Trade name: Disposable Semi Automatic Biopsy Instrument
Common name: Biopsy Instrument
Classification name: Gastroenterology-urology biopsy instrument.
Model(s): A, B
Production code: KNW
Regulation number: 21 CFR 876.1075
Classification: Class II
Panel: Gastroenterology/Urology

3.0 Predicate Device Information

Manufacturer: M.D.L. S.r.l.
Device: SemiCut Semi-automatic Biopsy Needle

4.0 Device Description

The disposable semi automatic biopsy instrument (hereinafter referred to as biopsy instrument) is divided into A and B in accordance with different configuration. A contains semi automatic biopsy needle. B contains semi automatic biopsy needle and coaxial biopsy needle.

The disposable semi automatic biopsy instrument consists of cannula, stylet, protecting sheath and mechanical powering parts. The coaxial biopsy needle consists of canular housing, canula, marker, stylet with sharping, stylet without sharping (option), stylet housing and protecting sheath.

It is available in several gauge sizes and lengths. Both the A and B of the device have printed gauge size indicator that is color coded according to the various gauge sizes (yellow= 20G, pink= 18G, purple= 16 G, and green= 14G). The needles have a protecting sheath.

The disposable semi automatic biopsy instrument is loaded a semi automatic biopsy needle that is visible in ultrasound. The device is equipped with a beveled needle with centimeter markings and an echogenic distal tip for visualization during ultrasound imaging. Centimeter markings on the cannula surface permits an easy identification of the insertion depth with the maximum safety for the patient.During use, the position of the device is monitored using imaging technique. The inner stylet which has a triple face ultra-sharp tip to penetrate easily also into fibrous tissues is equipped with a slot/ groove (a 19mm specimen notch) to collect a biopsy specimen.

During use, the position of the device is monitored using imaging technique. The inner stylet is equipped with a slot (specimen notch) to collect a biopsy specimen.

The materials used for construction of disposable semi automatic biopsy instrument are typical for this type of medical device. The only material in direct patient contact is the stainless steel 06Cr19Ni10.

As the device is single use device, which is individually packaged sterile devices. The packaging is compatible with the product's EO sterilization method. The sterilization validation confirms the packaging is qualified bacterial film to maintain the sterilization condition of the device.

5.0 Indication for Use Statement

The Disposable Semi Automatic Biopsy Instrument is intended for obtaining percutaneous or surgical histological core samples from soft tissues such as breast, kidney, liver, lung and various soft tissue masses. The device is not intended for use in bone.

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 the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures

6.0 Summary of Non-Clinical Testing

Summary of non-clinical and performance testing- Bench testing was performed to evaluate the performance and functionality of the subject device against requirement specification. The subject device has been subjected to compliance testing according to, by FDA, recognized consensus standards ISO 9626, ISO 10993-7, ISO 10993-1, ISO 11607-1. Results from testing performed confirms that the design requirement specification and user needs have been met. The subject device is confirmed to be safe and effective for the intended use.

7.1 Sterilization and shelf life of disposable semi automatic biopsy instrument is delivered sterile and have successfully been tested according to ISO 11607- 1. The label shelf life is 3 years.
7.2 Biocompatibility testing of disposable semi automatic biopsy instrument has successfully been tested for cytotoxicity, sensitization, intracutaneously irritation, acute systemic toxicity and material medicated pyrogenicity. The test results verify that the biocompatibility criteria given in ISO 10993 are fulfilled. Disposable automatic core biopsy instrument concludes that disposable automatic core biopsy instrument is non-toxic and biocompatible.
7.3 Performance testing – Bench: The performance of disposable semi automatic biopsy instrument has been verified. Tests as described in table 1 have been completed.

Table 1: Performance testing summary – Bench

Test Item	Description
Depth projection	To confirm that subject device will not extend over the stylet tip during use. Conformity has been demonstrated.
Penetration force	To confirm that the penetration force of the subject device is equivalent to predicate device. Conformity has been demonstrated.
Stiffness	To test the stiffness of the refill needle per ISO 9626. Conformity has been demonstrated.
Resistance to Breakage	To test the Resistance to Breakage per ISO 9626. Conformity has been demonstrated.
Bonding Strength	To test the Bonding Strength per ISO 7864 to confirm the connection firmness. Conformity has been demonstrated.
Biopsy Tissue Sample	To confirm that the subject device can successfully

Testing	retrieve biopsy specimen multiple times. Conformity has been demonstrated. Conformity has been demonstrated.
Ultrasound Visibility	To confirm that the invasive part of subject device is visible in the area guided by the puncture frame or within the ultrasound range. Conformity has been demonstrated.

7.0 Summary of Clinical Testing

No clinical study is included in this submission.

8.0 Technological Characteristic Comparison Table

Table 2- Comparison of Technology Characteristics

Item	Subject Device	Predicate Device
510(k) No.	K212820	K160316
Product Code	KNW	KNW
Regulation No.	21 CFR 876.1075	21 CFR 876.1075
Class	II	II
Intended Use	The Disposable Semi Automatic Biopsy Instrument is intended for obtaining percutaneous or surgical histological core samples from soft tissues such as breast, kidney, liver, lung and various soft tissue masses. The device is not intended for use in bone. 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 the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical	SemiCut Semi-Automatic Biopsy Needle is intended for obtaining percutaneous or surgical histological core samples from soft tissues such as breast, kidney, liver, lung and various soft tissue masses. The device is not intended for use in bone.

	procedures	
Anatomical sites	Specimens from soft tissue such as breast, kidney, liver, lung and various soft tissue masses	Specimens from soft tissue such as breast, kidney, liver, lung and various soft tissue masses.
Mechanism of Action	Single-hand semi-automatic activation	Single-hand semi-automatic activation
Device type	Semi Automatic biopsy gun	Semi Automatic biopsy gun
Visualization technique	Conventional imaging guidance equipment excluding MRI	Conventional imaging guidance equipment excluding MRI
Needle material	Stainless Steel. Only Stainless steel is in direct surgical contact with all soft tissues of the patient.	Stainless Steel
Needle diameter (Gauge)	14G,16G,18G,20G	14G,16G,18G
Needle length (mm)	60,100,130,160,200,250	70,90,100,110,120,150,160,200,250,300
Coaxial Needle diameter (Gauge)	13G,15G,17G,19G	13G,15G,17G,19G
Coaxial Needle length (mm)	70,78,100,108,130,138,170,178	52,53,72,73,82,83,93,132,133,143,160,182,183,184,233
Color Depiction	Per ISO 6009:2016: Yellow= 20G, Pink= 18G, Purple= 16 G, and Green= 14G	Not publicly available
Cannula and Stylet	The cannula is designed with an outer cutting cannula having a sharpened tip and an inner stylet with sample slot(a 19mm specimen notch).	The cannula is designed with an outer cutting cannula having a sharpened tip and an inner stylet with sample slot(a 20mm specimen notch).
Needle Advancement and Tissue Access	Biopsy Needle with guillotine coring provide the clinician with the same single automatic advancement for fixed sample length for tissue penetration and cutting.	Single or two-stage (sequential) automatic stylet advancement with different needle designs
Activation force	Single-hand automatic activation	Single-hand automatic activation
Specimen notch size	10mm,20mm	10mm,20mm
Penetration Depth	10mm,20mm	10mm,20mm

Sterile	Ethylene Oxide, SAL: 10^{-6}	Ethylene Oxide
Shelf Life	3 years	5 years
Single Use	Single Use	Single Use
Labeling	Conform with 21 CFR 801	Conform with 21 CFR 801
Performance Comparison testing	Comparative test of penetration force, stiffness, resistance to breakage, bonding strength and depth projection and tissue sample extraction testing on the current subject device and the predicate device have been performed.	
Biocompatibility	Conform with ISO10993-1 (ISO10993-4, ISO10993-5, ISO10993-10, ISO10993-11)	Conform with ISO 10993 standards

The technological characteristics of the subject device are identical to those of predicate device. The subject device has the same basic design as the predicate device. The comparison between the subject and predicate devices is based on the following:

- Same intended use
- Same indications for use
- Similar material types that meet ISO 10993 biocompatibility requirements
- Same sterilization methods
- Same fundamental technology/principal of operation/user interface

The disposable biopsy device needle designs display minor differences between the subject device and the predicate devices for gauge and needle length. The Max Needle gauge of the current device are bigger than those of the predicate device, but the comparative performance testing results per FDA recognized standards ISO 9626 and ISO 7864 on the subject device and the predicate device shown there is no significant risk raised by the difference.

9.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicated device in K160316 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.