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: K212822
Trade/Device Name: Disposable Coaxial Biopsy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: FCG
Dated: May 27, 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)*
K212822

Device Name
Disposable Coaxial Biopsy Needle

Indications for Use *(Describe)*
Disposable Coaxial Biopsy Needle is intended for use with biopsy devices cannula during soft tissue core biopsy procedures. The device is not intended for use in bone.

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.

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510(k) Summary

K212822

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 of Preparation: Jul.4,2022

2.0 Device Information

Trade name: Disposable Coaxial Biopsy Needle
Common name: Biopsy Needle
Classification name: Gastroenterology-urology biopsy instrument.
Model(s): 11G、13G、15G、17G、19G
Production code: FCG
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: MDL INTRO Coaxial Introducer Needles
510(k) number: K160316

4.0 Device Description

The disposable coaxial biopsy needle consists of canular housing, canula, marker, stylet with sharping, stylet without sharping, stylet housing and protecting sheath.
It is available in several gauge sizes and lengths.
The disposable coaxial biopsy needle (hereinafter referred to as coaxial biopsy needle) is divided into 11G、13G、15G、17G、19G in accordance with the outer diameter of canula and 70mm、78mm、100mm、108mm、130mm、138mm、170mm and 178mm in accordance with the length of canula.
The materials used for construction of disposable coaxial biopsy needle are typical for this type of medical device. The only material in direct patient contact is the stainless steel 06Cr19Ni10.
The disposable coaxial biopsy needle can be used with the matching biopsy needle under the guidance of medical imaging, as a channel for other biopsy needles to enter the body and obtain biopsy samples through negative pressure or cutting for clinical diagnosis or treatment. In clinical practice, doctors sometimes repeatedly puncture the target site for biopsy. At this time, the coaxial needle is configured, which provides a channel that the device can take multiple samples at the target site. That avoids repeated puncture and injury on the patient's skin surface.
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

Disposable Coaxial Biopsy Needle is intended for use with biopsy devices cannula during soft tissue core biopsy procedures. The device is not intended for use in bone.

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 7864, 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 disposable coaxial biopsy needle 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 coaxial biopsy needle 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 coaxial biopsy needle is non-toxic and biocompatible.

7.3 Performance testing – Bench: The performance of disposable coaxial biopsy needle 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 (over-throw) 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.
Mechanical durability	To confirm that subject device withstands the forces applied to the subject device during normal use. 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.
Qualification metal tubing/needle component	The stainless-steel tubing fulfills the requirement in ISO 9626 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods. 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.	K212822	K160316
Product Code	FCG	FCG
Regulation No.	21 CFR 876.1075	21 CFR 876.1075
Class	II	II
Intended Use	Disposable Coaxial Biopsy Needle is intended for use with biopsy devices cannula during soft tissue	Coaxial Introducer Needle is intended for use with biopsy devices cannula during soft tissue

	core biopsy procedures. The device is not intended for use in bone.	core biopsy procedures. The device is not intended for use in bone. The extent of histological abnormality cannot be reliably determined from it 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.
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.
Device type	Coaxial introducer needle with a blunt tip stylet	Coaxial introducer needle with a blunt tip stylet
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)	11G,13G,15G,17G,19G	13G,15G,17G,19G
Needle length (mm)	70、78、100、108、130、138、170、178	90,132,170,217
Cannula and Stylet	The cannula is designed with an outer cutting cannula having a sharpened tip and an inner stylet with sharping or without sharping.	The cannula is designed with an outer cutting cannula having a sharpened tip and an inner stylet with sharping or without sharping.
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 on the current subject device and the predicate device has 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

The Disposable Coaxial Biopsy Needle designs display minor differences between the subject device and the predicate devices for needle length. The Max Needle length 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.