November 10, 2021

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

Re: K212284
Trade/Device Name: Disposable Automatic Core Biopsy Instrument
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: KNW
Dated: August 11, 2021
Received: August 16, 2021

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
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K212284

Device Name
Disposable Automatic Core Biopsy Instrument

Indications for Use *(Describe)*
The Disposable Automatic Core Biopsy Instrument is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It 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

(K212284)

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

Name: Suzhou Leapmed Healthcare Corporation
Address: Wuzhong Science Park, NO.2 & NO.3 Building, 38# North Guandu Road, Wuzhong District, Suzhou City, 215100 Jiangsu, P.R.China
Tel: (+86) 512 66554498-8043
Contact: Yu Zhu

Designated Submission Correspondent

Name: Shanghai Truthful Information Technology Co., Ltd.
Address: Room 1801, No. 161 East Lujiazui Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Contact: Mr. Boyle Wang
Email: Info@truthful.com.cn

Date of Preparation: Oct.27,2021

2.0 Device Information

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

3.0 Predicate Device Information

Manufacturer: Bard Peripheral Vascular, Inc.
Device: Bard® Monapty® Disposable Core Biopsy Instrument
Bard® Max-Coreo® Disposable Care Biopsy Instrument
510(k) number: K133948

4.0 Device Description

The disposable automatic core biopsy instrument is divided into QZDA and QZDB in accordance with different configuration. QZDA contains automatic core biopsy instrument. QZDB contains automatic core biopsy instrument and coaxial biopsy needle.

The disposable automatic core biopsy instrument QZDA contains automatic core biopsy instrument and QZDB contains automatic core biopsy instrument and coaxial biopsy needle. The automatic core biopsy instrument consists of canula, stylet, protecting sheath and mechnical powering parts. The coaxial biopsy needle consists of canular housing, canula, marker, stylet, stylet housing and protecting sheath.

The subject device is a single use full core biopsy device. It is available in several gauge sizes and lengths. Both the QZDA and QZDB 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 automatic core biopsy instrument is a spring-loaded automatic biopsy needle that is visible in CT (computed tomography) and ultrasound. The device is equipped with a beveled needle with centimeter markings and an echogenic distal tip for visualization during ultrasound imaging. 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 automatic core 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 Automatic Core Biopsy Instrument is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It 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 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 as safe and as effective as the predicate.

7.1 Sterilization and shelf life: Disposable automatic core 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: Disposable automatic core 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 automatic core 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 (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.
Loading force	To confirm that the force to activate the subject device (release the spring) is not too low, resulting in unintentional activation during use. 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.
Tissue sample extraction test	To confirm that the subject device can successfully retrieve biopsy specimen multiple times. Conformity has been demonstrated
Tip configuration	To confirm that it is possible to take a biopsy specimen closer to nearby sensitive anatomy/structure compared to predicate device. Subject device shall have a tip dead-space that is shorter compared to predicate device. 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.
Compatibility	To confirm that the device is compatible with coaxial needle standardized sizes as per ISO 9626 has been

	applied.
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.	K212284	K133948
Product Code	KNW	KNW
Regulation No.	21 CFR 876.1075	21 CFR 876.1075
Class	II	II
Intended Use	The Disposable Automatic Core Biopsy Instrument is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not Intended for use in bone.	The core needle biopsy device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.
Anatomical sites	Specimens from soft tissue such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors.	Specimens from soft tissue such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors.
Mechanism of Action	Single puncture and sample multiple times	Single puncture and sample multiple times
Device type	Automatic biopsy gun, spring-operated	Automatic biopsy gun, spring-operated
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,20G

Needle length (mm)	100,160,200,250	100,160,200,250
Color Depiction	Per ISO 6009:2016: Yellow= 20G, Pink= 18G, Purple= 16 G, and Green= 14G	Per ISO 6009:2016: Yellow = 20G, Pink = 18G, Purple = 16G and Green = 14 G.
Cannula and Stylet	The cannula is designed with an outer cutting cannula having a sharpened tip and an inner stylet with sample slot.	Not publicly available
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.	Not publicly available
Activation force	Single-hand automatic activation	Not publicly available
Specimen notch size	18mm	18mm,19mm
Penetration Depth	22mm	22mm
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	Stiffness, Resistance to breakage, Resistance to corrosion, Sample collection space and smoothness, Connection firmness, Pressing parts/Pressing parts firing force, Cannula firing force, Sampling switch, Scale marks firmness, Total heavy metal content, Scale mark identification, Sampling structure, Penetration force, Biopsy Sample Testing, Ultrasound Visibility Testing	Stiffness, Resistance to breakage, Resistance to corrosion, Sample collection space and smoothness, Connection firmness, Pressing parts, Pressing parts firing force, Cannula firing force, Safety switch, Sampling switch, Scale marks firmness, Total heavy metal content, Scale mark identification, Sampling structure, Penetration force, Biopsy Sample Testing, Ultrasound Visibility Testing
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 specimen notch size and shelf life. The specimen notch size of the current device covered by the predicate device, also the validation report of shelf life shown the life time 3 years of the current device is scientific, reliable and effective. So we think the differences would not affect the substantial equivalence of the proposed device.

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 K133948 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.