April 3, 2023

Canyon Medical Inc.
Huiqi Jiang
RA
Building 3, Phase 2 Accelerator, No. 11 Yaogu Avenue
Jiangbei New Area
Nanjing, Jiangsu Province 210032
China

Re: K222865
Trade/Device Name: M Biopsy /SureCore Automatic Disposable Biopsy Needle, M Biopsy /SureCore Semi-Automatic Disposable Biopsy Needle, M Biopsy /SureAim Coaxial Biopsy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: March 3, 2023
Received: March 3, 2023

Dear Huiqi Jiang:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.04.03 11:20:56 -04'00'

Mark Trumbore, 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)*
K222865

Device Name
Automatic Disposable Biopsy Needle
Semi-automatic Disposable Biopsy Needle
Coaxial Biopsy Needle

Indications for Use *(Describe)*

Automatic Disposable Biopsy Needle:
Automatic Disposable Biopsy Needle is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lung, thyroid and lymph nodes. It is not intended for use in bone.

Semi-automatic Disposable Biopsy Needle:
Semi-Automatic Disposable Biopsy Needle is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lung, thyroid and lymph nodes. It is not intended for use in bone.

Coaxial Biopsy Needle:
Coaxial Biopsy Needle is intended for use as a guiding needle in obtaining core biopsy samples from soft tissues such as liver, kidney, prostate, spleen, lung, thyroid and lymph nodes. 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. 510(k) Submitter Information:

Submitter Name: Canyon Medical Inc.

Address: Building 3, Phase 2 Accelerator, No. 11 Yaogu Avenue, Jiangbei New Area, 210032, Nanjing, Jiangsu Province, People's Republic of China

Submission Correspondent: Ms. Huiqi Jiang, RA

E-mail: jhq@canyonmedical.com.cn

Telephone: +86-13241196637

2. Date of Preparation: January 24, 2023

3. Subject Device(s) Information:

Common Name:	Automatic Disposable Biopsy Needle
	Semi-automatic Disposable Biopsy Needle
	Coaxial Biopsy Needle
Trade Name:	M·Biopsy /SureCore Automatic Disposable Biopsy Needle
	M·Biopsy /SureCore Semi-automatic Disposable Biopsy Needle
	M·Biopsy /SureAim Coaxial Biopsy Needle
Regulation Number:	21 CFR 876.1075
Classification Name:	Instrument, Biopsy
Device Class:	II
Product Code:	KNW
Review Panel:	Gastroenterology/Urology

4. Predicate Device(s) Information:

Subject device	Predicate device
Automatic Disposable Biopsy Needle	K133948 BARD® MAX-CORE® Disposable Core Biopsy Instrument
Semi-automatic Disposable Biopsy Needle	K171953 BARD® MISSION® Disposable Core Biopsy Instrument
Coaxial Biopsy Needle	K171953 BARD® TRUGUIDE® Disposable Coaxial Biopsy Needle

5. Device Description

Automatic Disposable Biopsy Needle, Semi-automatic Disposable Biopsy Needle and Coaxial Biopsy Needle are hand-operated, non-electronic, surgical instruments.

Automatic Disposable 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. Automatic Disposable Biopsy Needle is first loaded and then inserted into the edge of the target tissue. Then, the inner needle rod is threaded into the target lesion (automatic firing), then, the outer needle tube is fired to push forward, and the tissue sample is cut through the relative movement of the outer needle tube and the inner needle rod of the biopsy needle, later, the tissue sample is cut off and stored in the sampling groove. Finally, specimen was removed after withdrawing the biopsy needle.

Semi-automatic Disposable Biopsy Needle 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.

Coaxial Biopsy Needle 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 needle.

All of these devices 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 devices can’t be used under MRI.

6. Indications for Use

Automatic Disposable Biopsy Needle is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lung, thyroid and lymph nodes. It is not intended for use in bone.

Semi-Automatic Disposable Biopsy Needle is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lung, thyroid and lymph nodes. It is not intended for use in bone.

Coaxial Biopsy Needle is intended for use as a guiding needle in obtaining core biopsy samples from soft tissues such as liver, kidney, prostate, spleen, lung, thyroid and lymph nodes. It is not intended for use in bone.

7. Technical Characteristics

The subject devices are substantially equivalent to the predicate devices in terms of intended use and technological characteristics. The differences 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
Automatic Disposable Biopsy Needle	K133948 BARD® MAX-CORE® Disposable Core Biopsy Instrument
Semi-automatic Disposable Biopsy Needle	K171953 BARD® MISSION® Disposable Core Biopsy Instrument
Coaxial Biopsy Needle	K171953 BARD® TRUGUIDE® Disposable Coaxial Biopsy Needle

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

Item	Subject Device-Canyon	Predicate Device-Bard
Device	Automatic Disposable Biopsy Needle	K133948 BARD® MAX-CORE® Disposable Core Biopsy Instrument
Classification	Class II	Same as subject device
Product Code	KNW	Same as subject device
Regulation Number	21 CFR 876.1075	Same as subject device
Regulation Name	Gastroenterology-Urology Biopsy Instrument	Same as subject device
Indications for Use	Intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lung, thyroid and lymph nodes. It is not intended for use in bone.	Same as subject device
Target Population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Same as subject device
Operation Mechanics	Single hand automatic activation	Same as subject device
Gauge	12G, 14G, 16G, 18G, 20G	14G, 16G, 18G, 20G
Length (mm)	100, 130, 160, 200, 250	100, 160, 200, 250
Penetration Depth (mm)	11, 22	Same as subject device
Slot Size (mm)	18	18, 19
Sterilization	EO Sterilization	Same as subject device
Single Use	Yes	Yes
Patient-contacting Infomarion	Externally communicating device, in contact with the patient for a limited duration (no more than 24 hours)	Same as subject device
Biocompatibility	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts

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

Item	Subject Device-Canyon	Predicate Device-Bard
Device	Semi-automatic Disposable Biopsy Needle	K171953 BARD® MISSION® Disposable Core Biopsy Instrument
Classification	Class II	Same as subject device
Product Code	KNW	Same as subject device
Regulation Number	21 CFR 876.1075	Same as subject device
Regulation Name	Gastroenterology-Urology Biopsy Instrument	Same as subject device
Indications for Use	Intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lung, thyroid and lymph nodes. It is not intended for use in bone.	Same as subject device
Target Population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Same as subject device
Operation Mechanics	Single hand semi-automatic activation	Same as subject device
Gauge	14G, 16G, 18G, 20G	14G, 16G, 18G, 20G
Length (mm)	60, 100, 130, 160, 200, 250, 300	60, 100, 160, 200, 250
Penetration Depth (mm)	10, 20	Same as subject device
Sterilization	EO Sterilization	Same as subject device
Single Use	Yes	Yes
Patient-contacting Information	Externally communicating device, in contact with the patient for a limited duration (no more than 24 hours)	Same as subject device
Biocompatibility	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts

Table 3. Comparison of the Coaxial Biopsy Needle to the predicate device.

Item	Subject Device-Canyon	Predicate Device-Bard
Device	Coaxial Biopsy Needle	K171953 BARD® TRUGUIDE® Disposable Coaxial Biopsy Needle
Classification	Class II	Same as subject device
Product Code	KNW	Same as subject device
Regulation Number	21 CFR 876.1075	Same as subject device
Regulation Name	Gastroenterology-Urology Biopsy Instrument	Same as subject device
Indications for Use	Intended for use as a guiding needle in obtaining core biopsy samples from soft tissues such as liver, kidney, prostate, spleen, lung, thyroid and lymph nodes. It is not intended for use in bone	Same as subject device
Operation Mechanics	Single hand automatic activation	Same as subject device
Target Population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Same as subject device
Gauge	13G, 15G, 17G, 19G	11G, 13G, 15G, 17G, 19G
Sterilization	EO Sterilization	Same as subject device
Single use	Yes	Yes
Patient contacting	Externally communicating device, in contact with the patient for a limited duration (no more than 24 hours)	Same as subject device
Biocompatibility	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts

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 indications for use
• Same material types that meet ISO 10993 biocompatibility requirements
• Same sterilization methods
• Same fundamental technology

There is no significant risk raised by the difference.

8. Summary of Non-Clinical Testing

Summary of non-clinical and performance 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 series standards, ISO 11607-1, ISO 11607-2, ASTM F 1980 etc. Results from testing performed confirm the design requirement.

1) Biocompatibility

The subject devices are externally communicating medical devices with tissue less than 24h which means limited duration. Therefore, as per “Table A.1: Biocompatibility Evaluation Endpoints” of FDA guidance, following items shall be carried out.

No.	Test Item	Standard
1	Cytotoxicity	ISO10993-5:2009
2	Maximization Sensitization	ISO10993-10:2010
3	Intracutaneous Reactivity	ISO10993-10:2010
4	Acute Systemic Toxicity	ISO10993-11:2017
5	Pyrogen Test	ISO10993-11:2017/ USP General Chapter <151>
6	Hemolysis	ISO 10993-4:2017

2) Package Validation

The primary package of the proposed device is intended to maintain the sterility of the product during its claimed shelf life. The integrity performance as per ISO 11607-1:2019 and ISO 11607-2:2019 is carried out.

3) Transport

Subject devices are processed by compression, first vibration, shock and second vibration, and then check. The result indicates that packaging is not damaged.

4) Shelf Life

Accelerated aging was used to simulate the storage of 5 years, then the physical performance tests, chemical performance tests as well as the package integrity tests were performed on the accelerated aged samples. The test results demonstrate that the aged samples complied with the pre-determined acceptance criteria.

5) Comparative Claims/Performance Comparison with predicate devices

The test was conducted to the predicate device and subject device to compare their performance, including scale mark identification, puncture force, biopsy sample testing, stiffness, resistance to breakage, resistance to corrosion, joint strength, total heavy metal content.

6) EO/ECH Resudial

Examination of the EO and ECH residuals have been conducted in accordance with ISO 10993-7:2008+Amd.1:2019 to evaluate whether the sterilized proposed device comply with the above selected allowable limits, and the results meet the requirements.

9. Preclinical (Animal) Studies

Bench testing is sufficient to demonstrate performance of the device. No preclinical testing of the subject device is necessary.

10. Clinical Test

No. Use of biopsy needle is proven technology and is well accepted by the medical community. Performance Test is sufficient to demonstrate safety and effectiveness of the subject devices with the predicate devices.

11. Conclusion

The differences between both devices are insignificant in terms of safety and effectiveness. The conclusions drawn from information above demonstrate that the proposed devices are as safe, as effective, and performs as well as the legally marketed predicate devices and raises no new risks of safety or effectiveness.