January 17, 2024

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

Re: K233031
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: September 25, 2023
Received: September 25, 2023

Dear Mingzhi Jin:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233031

Device Name
M·Biopsy /SureCore Automatic Disposable Biopsy Needle,
M·Biopsy /SureCore Semi-automatic Disposable Biopsy Needle,
M·Biopsy /SureAim 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, lymph nodes, breast and muscle. 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, lymph nodes, breast and muscle. 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, lymph nodes, breast and muscle. 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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1. 510(k) Owner

Canyon Medical Inc.

2. Submission Correspondent

Submitter: Ms. Mingzhi Jin, RA

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

3. Date of Preparation: January 13, 2024

4. 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

5. Predicate Device(s) Information

Subject device	**Predicate device - K222865**
Automatic Disposable Biopsy Needle	Automatic Disposable Biopsy Needle
Semi-automatic Disposable Biopsy Needle	Semi-automatic Disposable Biopsy Needle
Coaxial Biopsy Needle	Coaxial Biopsy Needle

6. 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 cannot be used under MRI.

7. 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, lymph nodes, breast and muscle. 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, lymph nodes, breast and muscle. 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, lymph nodes, breast and muscle. It is not intended for use in bone.

8. Purpose of Submission

The purpose of this submission is to introduce some modifications to the products

base on K222865.

1) Extend indications;

2) Add a component (swab) which can be used optionally to help take the biopsy specimen for further diagnosis preparation to the Automatic and Semi-automatic Disposable Biopsy Needle;

3) Add some models within previous specifications (K222865). The specifications of the new models are within the previously approved specification range (Automatic Disposable Biopsy Needle are available in specification range from 12G to 20G; Semi-automatic Disposable Biopsy Needle are available in specification range from 14G to 20G; Coaxial Biopsy Needle are available in specification range from 13G to 19G).

9. 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.

The technological characteristics of the subject devices are identical to those of predicate devices, with the exception of the following design changes:

1) More soft tissues types for indication - breast and muscle

2) A new component swab which can be used optionally to help take the biopsy specimen for further diagnosis preparation

3) Add some models within previous specifications (K222865)

Equivalence has been identified as follows:

Subject device	**Predicate device - K222865**
Automatic Disposable Biopsy Needle	Automatic Disposable Biopsy Needle
Semi-automatic Disposable Biopsy Needle	Semi-automatic Disposable Biopsy Needle
Coaxial Biopsy Needle	Coaxial Biopsy Needle

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

Item	Subject Device-Canyon	Predicate Device-Canyon	Comments
Device	Automatic Disposable Biopsy Needle	K222865 Automatic Disposable Biopsy Needle	
Classification	Class II	Class II	Same
Product Code	KNW	KNW	Same
Regulation Number	21 CFR 876.1075	21 CFR 876.1075	Same
Regulation Name	Gastroenterology-Urology Biopsy Instrument	Gastroenterology-Urology Biopsy Instrument	Same
Indications for Use	Intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lung, thyroid, lymph nodes, breast and muscle. It is not intended for use in bone.	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.	This change is to add new indications (breast and muscle). As for new indications, Canyon conducted sampling performance comparison with previously chosen predicate in K222865 to ensure the biopsy needles can be used on the new types of soft tissues.
Target Population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities	Same
Operation Mechanics	Single hand automatic activation	Single hand automatic activation	Same
Gauge	12G, 14G, 16G, 18G, 20G	12G, 14G, 16G, 18G, 20G	Same
Length (mm)	100, 130, 160, 200, 250	100, 130, 160, 200, 250	Same
Penetration Depth (mm)	11, 22	11, 22	Same
Slot Size (mm)	18	18	Same
Sterilization	EO Sterilization	EO Sterilization	Same
Single Use	Yes	Yes	Same
Patient-contacting Infomarion	Externally communicating device, in contact with the patient for a limited duration (no more than 24 hours)	Externally communicating device, in contact with the patient for a limited duration (no more than 24 hours)	Same
Biocompatibility	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts	Same

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

Item	Subject Device-Canyon	Predicate Device-Canyon	Comments
Device	Semi-automatic Disposable Biopsy Needle	K222865 Semi-automatic Disposable Biopsy Needle	
Classification	Class II	Class II	Same
Product Code	KNW	KNW	Same
Regulation Number	21 CFR 876.1075	21 CFR 876.1075	Same
Regulation Name	Gastroenterology-Urology Biopsy Instrument	Gastroenterology-Urology Biopsy Instrument	Same
Indications for Use	Intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lung, thyroid, lymph nodes, breast and muscle. It is not intended for use in bone.	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.	This change is to add new indications (breast and muscle). As for new indications, Canyon conducted sampling performance comparison with previously chosen predicate in K222865 to ensure the biopsy needles can be used on the new types of soft tissues.
Target Population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities	Same
Operation Mechanics	Single hand semi-automatic activation	Single hand semi-automatic activation	Same
Gauge	14G, 16G, 18G, 20G	14G, 16G, 18G, 20G	Same
Length (mm)	60, 100, 130, 160, 200, 250, 300	60, 100, 130, 160, 200, 250, 300	Same
Penetration Depth (mm)	10, 20	10, 20	Same
Sterilization	EO Sterilization	EO Sterilization	Same
Single Use	Yes	Yes	Same
Patient-contacting Information	Externally communicating device, in contact with the patient for a limited duration (no more than 24 hours)	Externally communicating device, in contact with the patient for a limited duration (no more than 24 hours)	Same
Biocompatibility	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts	Same

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

Item	Subject Device-Canyon	Predicate Device-Canyon	Comments
Device	Coaxial Biopsy Needle	K222865 Coaxial Biopsy Needle	
Classification	Class II	Class II	Same
Product Code	KNW	KNW	Same
Regulation Number	21 CFR 876.1075	21 CFR 876.1075	Same
Regulation Name	Gastroenterology-Urology Biopsy Instrument	Gastroenterology-Urology Biopsy Instrument	Same
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, breast and muscle. It is not intended for use in bone	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.	This change is to add new indications (breast and muscle). As for new indications, Canyon conducted sampling performance comparison with previously chosen predicate in K222865 to ensure the biopsy needles can be used on the new types of soft tissues.
Operation Mechanics	Single hand automatic activation	Single hand automatic activation	Same
Target Population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities	Same
Gauge	13G, 14G, 15G, 16G, 17G, 18G, 19G	13G, 15G, 17G, 19G	This change is to add new gauges, the gauges to be added are all within the previous cleared specifications of K222865.
Sterilization	EO Sterilization	EO Sterilization	Same
Single use	Yes	Yes	Same
Patient contacting	Externally communicating device, in contact with the patient for a limited duration (no more than 24 hours)	Externally communicating device, in contact with the patient for a limited duration (no more than 24 hours)	Same
Biocompatibility	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts	Same

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:

- Similar 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.

10. Summary of Non-Clinical Testing

Based on the purpose of this submission and as for the targeted design changes, we explicate and support with following:

10.1 As for indication extension

We conducted in vivo biopsy sampling from animal to compare the sampling performance of the subject devices and comparator devices (K133948 and K171953) , and the results indicated no substantial difference.

10.2 As for the addition of swab

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 11607-1, ISO 11607-2, ASTM F 1980 etc.

1) Biocompatibility

Since this component does not contact with the patient, therefore, biocompatibility test is unnecessary.

2) Package Validation and Transport

The swab is packaged in the previous package of Automatic Disposable Biopsy Needle and Semi-automatic Disposable Biopsy Needle without any other modification, therefore, no more test is carried out.

3) Sterility test

In order to ensure the sterility, the sterility test is carried out and the result meets the requirement.

4) Swab performance and shelf life

Overall requirement: the swab shall can help take the soft tissue

Performance 1: the tissue strip should be successfully removed from the sampling tank, and there should be no impurities such as dander (exfoliation of the swab) in the tissue strip.

Performance 2: after helping take soft tissue, the swab head should be complete, no broken, and no residual tissue strip on the swab head.

Performance 3: shelf life: 5 years

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

5) EO/ECH Residual

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. EO/ECH residual testing is based on the whole product of biopsy needle and the swab.

10.3 As for the addition of product models

Since the models to be added are all within the previous cleared specifications of K222865. Therefore, as this change, no more tests are needed.

11. Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the proposed subject devices are as safe, as effective, and performs as well as the legally marketed predicate devices and raises no new questions of safety or effectiveness.

The differences between both devices are insignificant in terms of safety and effectiveness.