July 11, 2025

Carbon (Shenzhen) Medical Device Co., Ltd.
% Jishan Jin
Regulatory Affairs
Linnwell International Certification Consulting Co., Ltd.
First Floor, Building 1, No. 333 Wanfang Road,
Minhang District
Shanghai, 201112
China

Re: K243296
Trade/Device Name: Disposable Biopsy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: October 13, 2024
Received: October 18, 2024

Dear Jishan 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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)*
K243296

Device Name
Disposable Biopsy Needle

Indications for Use *(Describe)*
The Disposable Biopsy Needle is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate. 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.

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510(k) Summary

[As required by 21 CFR 807.92(c)]

1. Submission Information

510(k) Number:	K243296
Date:	July 9, 2025
Type of 510(k) Submission:	Traditional submission
Applicant:	Carbon (Shenzhen) Medical Device Co., Ltd. Room 203, Building B, 5# Skyworth Innovation Vally, No. 1 Tangtou Road, Tangtou Community, Shiyan Street, Bao'an District, 518102 Shenzhen, PEOPLE'S REPUBLIC OF CHINA Contact: Ye Min Title: Quality Manager Tel: +86 13622306079 Email: ye.min@carbonmed.cn

2. Device Description

Trade/Device Name:	Disposable Biopsy Needle
Common Name:	Disposable Biopsy Needle
Device Classification Name:	Gastroenterology-urology biopsy instrument
Regulation Number:	21 CFR 876.1075
Product Code:	KNW
Device Class:	Class II

3. Predicate Device

Trade/Device Name:	Bard® Max-Core® Disposable Core Biopsy Instrument
510(k) Number	K133948
Regulation number	876.1075
Regulation Name	Gastroenterology-urology biopsy instrument
Regulation Class	Class II
Product Code	KNW
Manufacture	Carbon (Shenzhen) Medical Device Co., Ltd.

4. Indication for use

The Disposable Biopsy Needle is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate. It is not intended for use in bone.

5. Device Description

The disposable biopsy needle is a sterile, spring loaded, disposable percutaneous soft tissue biopsy instrument. The disposable biopsy needle consists of a cannula, an inner stylet, a mechanical power device and a protective cover. It is used to obtain tissue samples for tissue biopsy, suitable for tissue biopsy of various organs such as the kidney, liver, prostate etc. The needle need to be inserted by a qualified physician under ultrasound guidance. The button of the mechanical power unit comply with the color coding requirements of ISO 6009, i.e. 18 gauge = Pink. The disposable biopsy needle includes three models: CMBNA/1810, CMBNA/1815, CMBNA/1820.

6. Comparison of Technological Characteristics With Predicate Device

Parameters	Subject Device	Predicate Device	Comparison
510(k) Number	K243296	K133948	--
Trade/Device Name	Disposable Biopsy Needle	Bard® Max-Core® Disposable Core Biopsy Instrument	--
Model	CMBNA/1810, CMBNA/1815, CMBNA/1820	MC1810, MC1816, MC1820 (Other models are not included in this substantial equivalence discussion)	--
Owner	Carbon (Shenzhen) Medical Device Co., Ltd.	C. R. Bard, Inc.	--
Regulation number	21 CFR 876.1075	21 CFR 876.1075	Same
Product Code	KNW	KNW	Same
Classification	Class II	Class II	Same
Indications for use	The Disposable Biopsy Needle is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate. 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.	Subset Note 1
Soft Tissue Organ Examples	Soft tissue organs such as liver, kidney, prostate.	Soft tissue organs such as liver, kidney, prostate, spleen, lymph nodes, abdomen, thyroid, testes, bladder, lung, breast.	
Type of use	Prescription use	Prescription use	Same
Patient population	Individuals requiring biopsy for sampling of soft tissue abnormalities	Individuals requiring biopsy for sampling of soft tissue abnormalities	Same
Gauge x Length	18G×100mm, 18 G×150mm, 18 G×200mm	18G×10 cm, 18G×16 cm, 18G×20 cm	Similar Note 2
Penetration depth	21mm	22 mm	Similar Note 2
Single use	Yes	Yes	Same
Sterile supply	Yes	Yes	Same
Sterilization method	Ethylene oxide	Ethylene oxide	Same
SAL	10^{-6}	10^{-6}	Same
Mechanics of Action	Spring operated	Spring operated	Same
Sample notch	18mm	18mm	Same

size			
Mode of action	Single puncture and samples	Single puncture and samples	Same
Number of Samples	One or more	One or more	Same
Method of placement	Percutaneous puncture	Percutaneous puncture	Same
Visualization applications	Ultrasound	X-ray, ultrasound, CT, etc.	Subset Note 3
Safety features	Locking function: The needle cannot be activated after the slide is locked	Undisclosed	Same Note 5
Principle of operation	It is a side-notch biopsy gun. A hand-operated, non-electronic, surgical instrument designed for the automatic extraction of a small tissue sample from an anatomical structure, while causing minimal surrounding tissue damage, for tissue pathological testing. It cannot be use for bone tissue biopsy.	It is a side-notch biopsy gun. A hand-operated, non-electronic, surgical instrument designed for the automatic extraction of a small tissue sample from an anatomical structure, while causing minimal surrounding tissue damage, for tissue pathological testing. It cannot be use for bone tissue biopsy.	Same
Package	5 blister packs with Tyvek lids in a cardboard shelf box with the IFU	5 blister packs with Tyvek lids in a cardboard shelf box with the IFU	Same
Material (Contact with human body)	Outer cannula: Stainless steel	Cannula: Stainless steel	Same Note 4
	Inner stylet: Stainless steel	Undisclosed	
	Medical Fluid: Polydimethylsiloxane	Undisclosed	
	Left and right half tubes: Polyoxymethylene copolymer (POM)		
	Mechanical power unit: Acrylonitrile Butadiene Styrene (ABS)+ Polyoxymethylene copolymer (POM)	Undisclosed	
	Protective cover: Polypropylene (PP)	Undisclosed	
Nature of body contact	Outer cannula, Inner stylet, Medical Fluid, Left and right half tubes: Tissue/bone/dentin, Limited	Cannula & Stylet: Tissue/bone/dentin, Limited	Same
	Mechanical power unit, protective cove: Intact skin, Limited	Handle: Intact skin, Limited	
EO residue	Meet ISO 10993-7	Meet ISO 10993-7	Same
ECH residue	Meet ISO 10993-7	Meet ISO 10993-7	
Shelf life	2 years	3years	Similar Note 4

Bacterial endotoxin	<20EU/set	<20EU/set	Same

Differences between New device and Predicate Devices:

Note 1:

The indications of the subject device are fewer than those of Bard® Max-Core® because the current declared indications for the predicate device cover all specifications of 14G-20G biopsy needles, while the subject device only has one specification of 18G. Therefore, the indicated soft tissues are only liver, kidney and prostate.

Note 2:

The subject device is available in lengths of 100mm, 150mm and 200mm, while the predicate device is available in 100mm, 160mm and 200mm. There is no difference between the two in the maximum and minimum length, only a slight difference in the middle specifications. This difference does not affect clinical use, as the physician will choose the appropriate length of the biopsy needle according to the patient's situation. The width and length of the biopsy needle can be found on the label and labeling to ensure that the physician is aware of it.

There are also subtle differences in the penetration depth between the subject device and the predicate device. The penetration depth can also be found in the user manual, and it is up to the doctor to decide whether the advance distance is appropriate, so this difference does not raise any safety or effectiveness issues.

Note 3:

The subject device is only visible under ultrasound and has fewer visualization technology than the predicate device. We have clarified the use conditions of the subject device in the user manual and provided a B-ultrasound image display test report to prove its visibility, so this difference does not have any safety or effectiveness issues.

Note 4:

The shelf life and materials of the subject device may differ from those of the predicate device. We have demonstrated the biosafety, stability, and packaging integrity of the subject device through non-clinical bench testing. Therefore, these differences do not raise any safety or effectiveness issues.

7. Non-clinical Testing

All nonclinical testing performed on new devices is to demonstrate the substantial equivalence to the predicate devices. Tests setup and execution are performed in accordance with applicable standards. Results of the testing demonstrate the compliance to the standards and matching the performance of new devices to the predicate devices. The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility test

- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity;
- ISO 10993-10 Fourth edition 2021-11Biological evaluation of medical devices - Part 10: Tests for skin sensitization;
- ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation;
- ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices - Part 11: Tests for

systemic toxicity;

- ISO 10993-4 Third edition 2017-04 Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood;
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials;
- USP-NF M98900_01_01 <151> Pyrogen Test (USP Rabbit Test);

Packaging verification

- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection;
- ASTM F1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration;
- ASTM F88/F88M-2021 Standard Test Method for Seal Strength of Flexible Barrier Materials;
- DIN 58953-6:2023 Sterilization- Sterile supply -Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized;
- USP-NF M98810_01_01 <71> Sterility Tests;

Sterilization and shelf life

- ISO 11135 Second edition 2014-07-15 Sterilization of health-carISOe products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)];
- ISO 10993-7 Second edition 2008-10-15 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)];
- USP-NF M98830_02_01 <85> Bacterial Endotoxins Test;
- ANSI AAMI ST72:2019 Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing;
- ISO 11737-2 Third edition 2019-12 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process;
- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D4169-23 Standard Practice for Performance Testing of Shipping Containers and Systems;

Performance Test

- ISO 9626 Second edition 2016-08-01 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods;
- ISO 7864 Fourth edition 2016-08-01 Sterile hypodermic needles for single use - Requirements and test methods;
- ISO 6009 Fourth edition 2016-08-01 Hypodermic needles for single use - Colour coding for identification;

Sampling Verification Testing

In order to verify the sampling ability of the disposable biopsy needle, the biopsy needle was inserted into three different in vitro tissues (porcine liver, porcine kidney and canine prostate), and the mass and quality of the tissues were examined. The samples collected using the subject device were comparable to those collected using the predicate device.

The mechanical power unit of the biopsy needle was tested on in vitro tissues and pork, and 24 repeated sampling steps were completed as instructed in the instructions to evaluate whether the device could fire

correctly and whether the safety lock function was normal. All operations are smooth and meet the requirements of the acceptance criteria, which indicates that the disposable biopsy needle can work as intended.

8. Animal Study

Substantial equivalence does not depend on animal test data.

9. Clinical Testing

Substantial equivalence does not depend on clinical test data.

10. Substantial Equivalent (SE) Conclusion

Based on the device comparison information and non-clinical testing, the subject device is Substantially Equivalent (SE) to the predicate device which is US legally market device. Therefore, the subject device is determined as safe and effective.