January 24, 2025

Zhejiang CuraWay Medical Technology Co., Ltd.
Li Yin
Regulatory affairs specialist
Room 106, Building 1, No. 600, 21st Avenue,
Baiyang Sub-district, Qiantang New District
Hangzhou, Zhejiang 310018
China

Re: K241793
Trade/Device Name: Automatic Core Biopsy Instrument/ Semi-Automatic Core Biopsy Instrument/ Disposable Coaxial Biopsy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: December 27, 2024
Received: December 27, 2024

Dear Li Yin:

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
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.

Submission Number *(if known)*

K241793

Device Name

Automatic Core Biopsy Instrument/ Semi-Automatic Core Biopsy Instrument/ Disposable Coaxial Biopsy Needle

Indications for Use *(Describe)*

Automatic Core Biopsy Instrument is intended for use in obtaining biopsies from soft tissues such as breast, liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

Semi-Automatic Core Biopsy Instrument is intended for use in obtaining biopsies from soft tissues such as lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, and various soft tissue tumors. It is not intended for use in bone.

Disposable Coaxial Biopsy Needle is intended for use as a guiding needle in obtaining core biopsy samples from soft tissue such as lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid and various soft tissue tumors. It is designed for use with CuraWay Automatic Core Biopsy Instrument and CuraWay Semi-Automatic Core Biopsy Instrument. 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.

510(K) Summary
K241793

Company Name/Owner	Zhejiang CuraWay Medical Technology Co., Ltd.
Contact person/Author	Yin Li
Date prepared	January 24, 2025
Contact details Address	Room 106, Building 1, No. 600, 21st Avenue, Baiyang Sub-district, Qiantang New District, 310018 Hangzhou City, Zhejiang Province, China
Contact phone number	86-571-87016876
Trade name	Automatic Core Biopsy Instrument Semi-Automatic Core Biopsy Instrument Disposable Coaxial Biopsy Needle
Common name	Core Biopsy Instrument, Biopsy Needle
Classification name	Instrument, biopsy
Review panel	Gastroenterology/Urology
Regulation number	21 CFR 876.1075
Product code	KNW
Predicate device	BARD® MAX-CORE®Disposable Core Biopsy Instrument (K133948) Achieve Programmable Automatic Biopsy System (K141552) Bard® Mission® Disposable Core Biopsy Instrument (K171953) Bard® TruGuide® Disposable Coaxial Biopsy Needle (K171953)

1. Device Description

- **Automatic Core Biopsy Instrument**

Automatic Core Biopsy Instrument has seven models: BN-OCR-1, BN-OCR-2, BN-OCR-3, BN-OCR-6, BN-OCR-7, BN-OCR-8 and BN-OCR-9.

BN-OCR-1, BN-OCR-2 and BN-OCR-3 of Automatic Core Biopsy Instrument is automatic firing, and the structure is consisted of Inner Stylet, Cutting Cannula, Operating Handle, Actuation button, Depth stopper, Slide block and Protective sheath.

BN-OCR-6, BN-OCR-7, BN-OCR-8 and BN-OCR-9 of Automatic Core Biopsy Instrument has both automatic firing and delay firing options, the automatic firing mode releases the cannula and stylet in rapid sequence and captures a tissue sample with the push of a button. The delay firing method is used to verify the position of the sample notch in the target area prior to depressing the actuation button "A", which activates the cutting cannula, capturing the tissue sample. The structure is consisted of Inner Stylet, Cutting Cannula, Adjustable Knob (only for BN–OCR-7 and BN–OCR-9), Charging handle, Operating Handle, Security Lock (only for BN–OCR-8 and BN–OCR-9) and Protective Sheath.

Each model has various specifications depending on different sizes such as needle lengths, needle diameters, etc.

The cutting cannula has centimeter scales on it to provide reference for depth placement. In the distal area of the cutting cannula, an ultrasound enhancement is available to promote accurate placement under ultrasound or X-ray guidance, excluding MRI.

The Automatic Core Biopsy Instrument is single-use device, supplied in a sterile state sterilized by EO gas. A re-sterilization by users is not allowed. The shelf life is defined for 3 years, which is verified.

- **Semi-Automatic Core Biopsy Instrument**

The Semi-Automatic Core Biopsy Instrument has two models (BN-OCR-4, BN-OCR-5) according to whether there is a Safety limit slot.

The Semi-Automatic Core Biopsy Instrument consists of Inner stylet, Cutting cannula, Fixed handle, Windows, Safety switch, Plunger and Protective sheath. The needle is protected in a protective sheath.

Each model has various specifications depending on different sizes such as needle lengths, needle diameters, etc. The plunger is color-coded, which indicates gauge size of the needle.

The Cutting cannula has centimeter scales on it to provide reference for depth placement. In the distal area of the Cutting cannula, an ultrasound enhancement is available to promote accurate placement under ultrasound or X-ray guidance, excluding MRI.

The Semi-Automatic Core Biopsy Instrument is single-use device, supplied in a sterile state sterilized by EO gas. A re-sterilization by users is not allowed. The shelf life is defined for 3 years, which is verified.

- **Disposable Coaxial Biopsy Needle**

Disposable Coaxial Biopsy Needle has two models: BN-MAR-5, BN-MAR-6.

The Disposable Coaxial Biopsy Needle consists of Inner Stylet, Cutting cannula, Operating handle of Cutting cannula, Operating handle of Inner stylet, Depth stopper, Protective Sheath, Adaptor (optional) and Blunt needle (optional).

An adjustable depth stopper allows the user to restrict forward movement, localizing the needle tip to the biopsy site. The Depth Stopper is color-coded, which indicates gauge size of the needle. It is available in several needle gauge sizes and lengths.

Disposable Coaxial Biopsy Needle is intended for soft-tissue biopsy and designed as guiding needle for use with CuraWay disposable Biopsy Instruments/Needles such as CuraWay's Automatic Core Biopsy Instrument and CuraWay's Semi-Automatic Core Biopsy Instrument. The outer cannula is one gauge-size less than the compatible Biopsy Instrument/Needle, e.g., 19-gauge CuraWay Coaxial Biopsy Needle for a 20 gauge CuraWay Disposable Biopsy Needle or CuraWay Disposable biopsy instrument.

The Cutting cannula has numerical scales on it to provide reference for depth placement. In the distal area of the cutting cannula, an ultrasound enhancement is available to promote accurate placement under ultrasound or X-ray guidance excluding MRI.

The Disposable Coaxial Biopsy Needle is single-use device, supplied in a sterile state sterilized by EO gas. A re-sterilization by users is not allowed. The shelf life is defined for 3 years, which is verified.

2. Indications for use

Automatic Core Biopsy Instrument is intended for use in obtaining biopsies from soft tissues such as breast, liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

Semi-Automatic Core Biopsy Instrument is intended for use in obtaining biopsies from soft tissues such as lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, and various soft tissue tumors. It is not intended for use in bone.

Disposable Coaxial Biopsy Needle is intended for use as a guiding needle in obtaining core biopsy samples from soft tissue such as lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid and various soft tissue tumors. It is designed for use with CuraWay Automatic Core Biopsy Instrument and CuraWay Semi-Automatic Core Biopsy Instrument. It is not intended for use in bone.

3. Substantial equivalence comparison with predicate device

Detailed substantial comparison was made between subject device and predicate device.

Subject device	Predicate device 1	Predicate device 2	Comparison
Automatic Core Biopsy Instrument	BARD® MAX-CORE®Disposable Core Biopsy Instrument (K133948)	Achieve Programmable Automatic Biopsy System (K141552)	Refer to Table 1 below
Semi-Automatic Core Biopsy Instrument	Bard® Mission® Disposable Core Biopsy Instrument (K171953)	/	Refer to Table 2 below
Disposable Coaxial Biopsy Needle	BARD® TRUGUIDE® Disposable Coaxial Biopsy Needle (K171953)	/	Refer to Table 3 below

Table 1: Substantial equivalence comparison of Automatic Core Biopsy Instrument

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Comment
	Automatic Core Biopsy Instrument	**BARD® MAX-CORE® Disposable Core Biopsy Instrument**	**Achieve Programmable Automatic Biopsy System**	
Classification Regulation	876.1075	876.1075	876.1075	Same
Product Code	KNW	KNW	KNW	Same
510(k) Number	-	K133948	K141552	/
Indications for use	The Automatic Core Biopsy Instrument is intended for use in obtaining biopsies from soft tissues such as breast, 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.	The Achieve Programmable Automatic Biopsy System is intended for use in obtaining core biopsy samples from soft tissue such as kidney, liver, prostrate, spleen, lymph nodes, and various soft tissue masses. Not intended for use in bone. The Achieve Programmable Automatic Biopsy System is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with	Same

			partial or complete removal of the imaged abnormality.	
Operation mechanics	Automatic activation and Automatic mode and delay mode	Automatic activation	Automatic mode and delay mode	Same
Material of patient contact component	Stainless steel	Stainless steel	Stainless steel	Same
Body contact site	Breast, liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors	Liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors	Kidney, liver, prostrate, spleen, lymph nodes, various soft tissue masses and breast	Same
Structure	The Automatic Core Biopsy Instrument contains automatic activation type (BN-OCR-1, BN-OCR-2 and BN-OCR-3) and automatic and delay type (BN-OCR-6, BN-OCR-7, BN-OCR-8 and BN-OCR-9). Automatic activation type is consisted of inner stylet, cutting cannula, operating handle, slide block, actuation button, depth stopper and protective sheath. Automatic and delay type is	The device is consisted of handle and biopsy instrument. The biopsy instrument is composed of inner stylet and cutting cannula. Each needle has numerically ordered centimeter markings on the outer cannula to provide reference for depth placement. Needles feature an adjustable needle stop which allows the user to restrict forward movement, localizing the needle tip to the biopsy site.	The device is consisted of notched stylet, cutting cannula, firing buttons and charging handle.	Difference 1

	consisted of inner stylet, cutting cannula, adjustable knob, charging handle, operating handle, security lock and protective sheath. The cutting cannula has numerically ordered centimeter markings on it to provide reference for depth placement. An adjustable depth stopper allows the user to restrict forward movement, localizing the needle tip to the biopsy site. The operating handle is color-coded, which indicates gauge size of the needle.	Color coded stylet hubs indicate gauge size of needles available in a variety of gauge sizes and centimeter lengths.		
Visualization technique	The introduction of the needle into the body should be carried out under imaging guidance (ultrasound, X-Ray, CT, etc.)	The introduction of the needle into the body should be carried out under imaging control (ultrasound, X-Ray, CT, etc.).	Echogenic markings on both stylet tip and cannula help confirm the placement of the sample notch for precise ultrasound positioning.	Same
Nominal length of Cutting Cannula (mm)	80, 90, 100, 130, 150, 160,180, 200, 250	100, 160, 200, 250	60, 90, 110, 150, 200, 250	Difference 2

Needle size	14G, 16G, 18G, 20G	14G, 16G, 18G, 20G	14G, 16G, 18G, 20G	Same
Length of sample notch (mm)	18.5 mm	18mm, 19mm	20mm	Difference 3
Biocompatibility	ISO 10993 series standards	ISO 10093-1, ISO 10993-5 and ISO 10993-10	ISO 10093-1, ISO 10993-5 and ISO 10993-10	Same
Sterilization method	EO sterilization	EO sterilization	EO sterilization	Same
Single use	Yes	Yes	Yes	Same

- Difference 1: Structure
  The structure and working principle of subject device and predicate devices are basically the same. The components of subject device and predicate devices both include inner stylet, cutting cannula, operating handle, actuation button, and depth stopper, but they are named differently. The function of components of subject device and predicate devices are the same. The differences in design do not affect the safety and effectiveness of product. In sum, subject device and predicate devices have similar structure.

- Difference 2: Nominal length of Cutting Cannula
  It can be seen from the table above that subject device provides more selections on the nominal length of Cutting Cannula, namely 80mm, 130mm and 180mm. Considering the different shape of patients and the distance between needle insertion point and lesion, 80mm, 130mm and 180mm are provided by subject device. Besides, 80mm, 130mm and 180mm are within the length range (60mm to 250mm) of predicate devices. So this difference does not affect the safety and effectiveness of device.

- Difference 3: Length of sample notch

The length of sample notch of subject device is 18.5 mm, and the length of sample notch of predicate devices are 18mm, 19mm and 20mm. Although the lengths are not the same, the length of subject device is within the length range of predicate devices. So this difference does not affect the safety and effectiveness of device.

Conclusion

Comparison of the device in question with the predicate devices K133948 and K141552 is performed, and comparison items include indications for use, operation mechanics, material of patient contact component, body contact site, structure, visualization technique, nominal length of Cutting Cannula, needle size, length of sample notch, biocompatibility, sterilization method and single use. It can be concluded that subject device and predicate device perform the same function under the same clinical conditions. The differences between the subject device and predicate devices do not affect the safety and effectiveness. Therefore, they can be considered as equivalent devices.

Table 2: Substantial equivalence comparison of Semi-Automatic Core Biopsy Instrument

Comparison Elements	Subject Device	Predicate Device	Comment
Proprietary Name	Semi-Automatic Core Biopsy Instrument	Bard® Mission® Disposable Core Biopsy Instrument	-
Classification Regulation	876.1075	876.1075	Same
Product Code	KNW	KNW	Same
510(k) Number	-	K171953	-
Indications for use	Semi-Automatic Core Biopsy Instrument is intended for use in obtaining biopsies from soft tissues such as lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, and various soft tissue tumors. It is not intended for use in bone.	The BARD® MISSION® Disposable Core Biopsy Instrument is intended for use in obtaining biopsy samples from soft tissues such as from the lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, and various soft tissue tumors. It is not intended for use in bone.	Same
Operation mechanics	Semi-Automatic	Semi-Automatic	Same

Comparison Elements	Subject Device	Predicate Device	Comment
Material of patient content component	Stainless Steel	Stainless Steel	Same
Body contact site	Lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, and various soft tissue tumors.	Lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, and various soft tissue tumors.	Same
Structure	Component/ Design features: Inner stylet, Cutting cannula, Fixed handle, Windows, Safety switch, Plunger and Protective sheath, Centimeter marking, fixed handle, windows, ultrasound enhancement (offers enhanced ultrasound visibility of the Inner stylet and Cutting cannula). The plunger is color-coded, which indicates gauge size of the needle.	Component/Design features: Trocar stylet, Coaxial cannula, Depth stop, centimeter marks, Ergonomic grip design, Fire Ready Indicator, Penetration depth indicator, Echogenic technology (offers enhanced ultrasound visibility of the stylet needle and cutting cannula needle), Protective needle sheath. The plunger (is color coded according to the various gauge sizes.	Difference 1
Visualization technique	The introduction of the needle into the body should be carried out under imaging guidance (ultrasound,	The introduction of the needle into the body should be carried out under imaging guidance	Same

Comparison Elements	Subject Device	Predicate Device	Comment
	X-Ray, CT, etc.). excluding MRI.	(ultrasound, X-Ray, CT, etc.). excluding MRI.	
Nominal length of Cutting Cannula	8cm, 9cm, 10cm, 13cm, 15cm, 16cm, 18cm, 20cm, 25 cm	10cm, 16cm, 20cm, 25cm	Difference 2
Needle size	14G, 16G, 18G, 20G	14G, 16G, 18G, 20G	Same
Penetration depth	10mm and 20mm	10mm and 20mm	Same
Biocompatibility	ISO 10993 series standards	ISO 10993 series standards	Same
Sterilization method	EO sterilization	EO sterilization	Same
Single use	YES	YES	Same

- Difference 1: Structure
  The structure and working principle of Subject device and Predicate device are basically the same. The components are both including the Inner stylet, Cutting cannula, fixed handle, Plunger, and Protective sheath with identical appearances, but named differently. Both products are designed with two firing positions and support single-handed operation.

  Major differences in structure Compared to Predicate device:

  a. Fixed Handle: Fixed handle of Subject device adopts a structure of a rectangular cover shell and a base shell. Two complete circular rings are designed on the base shell to facilitate effective gripping during operation. In contrast, Predicate device features a symmetrical cover and base shell design, forming open semi-circular rings on both sides when combined, allowing effective gripping.

b. Safety Switch: Subject device includes a safety switch at the end of the fixed handle to prevent accidental firing during the puncture process, ensuring safe usage.
c. Window Design: The window of Subject device is marked with "10" and "20" indicator lines (with numbers) on both sides. When the plunger is pulled, a indicator line appears to show the firing length. Predicate device displays numbers （“0”，“10” or “20”）directly within the window without using indicator lines.

Above all, The subject device and predicate device have the same Fundamental Scientific Technology, including Mechanism/Mode of Action, and Energy Used/Delivered. These differences changes of structure are ergonomically designed and do not affect the safety and effectiveness of the product.

- Difference 2: Nominal length of Cutting Cannula

  Due to the different body shapes of patients and the different distances between different lesions and the needle entry point, clinical and market demand, subject product has increased 5 kinds of needle length of 8cm, 9cm, 13cm, 15cm and 18cm compared with the predicate product, this will not raise any safety issue.

The above mentioned differences do not raise new questions of safety and effectiveness.

Conclusion

Comparison of the device in question with the predicate devices K171953 is performed, and comparison items include indications for use, operation mechanics, material of patient contact component, body contact site, structure, visualization technique, nominal length of Cutting Cannula, needle size, penetration depths, biocompatibility, sterilization method and single use. It can be concluded that subject device and predicate device perform the same function under the same clinical conditions. The differences between the subject device and predicate devices do not affect the safety and effectiveness. Therefore, subject device can be considered as equivalent devices.

Table 3: Substantial equivalence comparison of Disposable Coaxial Biopsy Needle

Comparison Elements	Subject Device	Predicate Device	Comment
Proprietary Name	Disposable Coaxial Biopsy Needle	BARD® TRUGUIDE® Disposable Coaxial Biopsy Needle	-
Classification Regulation	876.1075	876.1075	Same
Product Code	KNW	KNW	Same
510(k) Number	-	K171953	-
Indications for use	Intended for use as a guiding needle in obtaining core biopsy samples from soft tissue such as lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid and various soft tissue tumors. It is designed for use with CuraWay Automatic Core Biopsy Instrument and CuraWay Semi-Automatic Core Biopsy Instrument. It is not intended for use in bone.	Intended for use in obtaining biopsy samples from soft tissues such as from the lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, and various soft tissue tumors. It is not intended for use in bone.	Same
Material of patient content component	Stainless Steel, TPE	Stainless Steel	Difference 1
Body contact site	Soft tissue such as lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid and various soft tissue tumors	lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, and various soft tissue tumors.	Same
Structure	● The Disposable Coaxial Biopsy Needle consists of Inner stylet, Cutting	● The BARD® TRUGUIDE® Disposable Coaxial Biopsy Needle is a	Difference 2

Comparison Elements	Subject Device	Predicate Device	Comment
	cannula, Operating handle of cutting cannula, Operating handle of Inner stylet, Blunt needle (optional), Depth stopper, Adapter (optional) and Protective sheath. ● Design features: Centimeter marks, Color Coding, Ultrasound enhancement.	three part device consisting of an outer cannula with an attached female luer-style lock hub, an inner stylet with an attached male luer-style lock hub, and a flexible slip ring style depth stop. ● Design features: Centimeter marks, Color Coding, Echogenic Enhancement	
Visualization technique	The introduction of the needle into the body should be carried out under imaging guidance (ultrasound, X-Ray, CT, etc.) excluding MRI	The introduction of the needle into the body should be carried out under imaging guidance (ultrasound, X-Ray, CT, etc.) excluding MRI	Same
Blunt needle	An optional blunt tip stylet is included with all gauge size Disposable Coaxial Biopsy Needles.	An optional blunt tip stylet is included with all 18- and 20-gauge BARD® TRUGUIDE® Coaxial Biopsy Needles.	Difference 3
Nominal length of Cutting Cannula	various sizes, min. 3cm to max. 21.6cm	7.0-17.8 cm	Difference 4
Needle size	13G, 15G, 17G, 19G	11G, 13G, 15G, 17G, 19G	Same
Connection type	Luer connection	Luer connection	Same
Biocompatibility	ISO 10993 series standards	ISO 10993 series standards	Same
Sterilization method	Yes, Ethylene Oxide sterilization	Yes, Ethylene Oxide sterilization	Same

Comparison Elements	Subject Device	Predicate Device	Comment
Single use	YES	YES	Same

- Difference 1: Material of patient content component

  The material used in Disposable Coaxial Biopsy Needle has been tested for biocompatibility in accordance with ISO 10993 for externally communicating devices in contact with tissue for 24 hours or less. The materials in direct patient contact include the Cutting cannula, Inner stylet, and Blunt needle made of stainless steel SUS304, as well as the Depth stopper made of TPE.
  Disposable Coaxial Biopsy Needle have successfully been tested for:
  - Cytotoxicity
  - Sensitization
  - Intracutaneously irritation
  - Acute Systemic Toxicity
  - Pyrogenicity

- Difference 2: Structure
  The structure and working principle of Subject device and Predicate device are basically the same, but the components named differently. The devices have same fundamental scientific technology, including design, mechanism/mode of action. The only major difference of design is the depth stopper: Depth stopper of Subject device is cylindrical structure (the diameter of the cylinder is narrow at the top and wide at the bottom), which integrates the function of installing protective sheath. The Predicate device is cylindrical structure with the same diameter of the cylinder.
  These changes are ergonomically designed and do not affect the safety and effectiveness of the product. So, similar structure and design concept.

- Difference 3: Blunt needle

The blunt tip stylet may be used to manipulate through soft tissue around vasculature or other organs to minimize the risk of unintentional damage to these areas. The company offers a more comprehensive selection of blunt needle types to reduce injury in clinical applications.

- Difference 4: Nominal length of Cutting Cannula
  Due to the different body shapes of patients and the different distances between different lesions and the needle entry point, clinical and market demand, subject product has increased more needle lengths compared with the predicate product.

The above mentioned differences do not raise new questions of safety and effectiveness.

Conclusion

Comparison of the device in question with the predicate devices K171953 is performed, and comparison items include indications for use, material of patient contact component, body contact site, structure, visualization technique, blunt needle, nominal length of Cutting Cannula, needle size, connection type, biocompatibility, sterilization method and single use. It can be concluded that subject device and predicate device perform the same function under the same clinical conditions. The differences between the subject device and predicate devices do not affect the safety and effectiveness. Therefore, the subject device can be considered as equivalent devices.

4. Summary of Non-Clinical Testing

CuraWay performed the following bench testing so as to demonstrate the intended use of the products.

4.1 Biological Testing

- In Vitro Cytotoxicity Test (ISO 10993-5: 2009)
- Intracutaneous Reactivity Test (ISO 10993-23: 2021)
- Skin Sensitization test (ISO 10993-10: 2021)
- Irritation or - Intracutaneous Reactivity (ISO 10993-10)
- Acute Systemic Toxicity Test (ISO 10993-11: 2017)
- Pyrogen Test (ISO 10993-11: 2017)

4.2 Sterilization validation

Sterilization validation is performed according to ISO 11135: 2014, EO and ECH are validated according to ISO 10993-7: 2008. SAL=10^{-6}.

The sterility test is carried out according to ISO 11737-2: 2019.

4.3 Packaging and shelf-life testing

The primary package of the proposed device is intended to maintain the sterility and performances of the product during its claimed shelf life. The testing is carried out in accordance with ASTM F1980: 2016.

4.4 Performance comparison with predicate devices

Comparison test was conducted between the subject devices and predicate devices to compare their performances, including appearance, dimensions, sampling performance, connection firmness, stiffness, toughness, resistance to corrosion, puncture force, chemical properties, etc.

5. Clinical data

No clinical data was provided.

6. Conclusion

The indications for use, design and nonclinical performance testing indicate that the technological characteristics of subject device are equivalent to that of predicate devices. In conclusion, it can be determined that subject device is substantially equivalent to predicate devices.