August 28, 2026

Zhejiang Curaway Medical Technology Co., Ltd.
Yin Li
Regulatory affairs specialist
Rm. 106, Bldg. 1, # 600, 21st Ave., Baiyang Sub-District, Qiantang New District
Hangzhou, Zhejiang 310018
China

Re: K260517
Trade/Device Name: Automatic Core Biopsy Instrument
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: July 31, 2026
Received: July 31, 2026

Dear Yin Li:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260517

Please provide the device trade name(s).

Automatic Core Biopsy Instrument

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) Summary

Company Name/Owner	Zhejiang CuraWay Medical Technology Co., Ltd.
Contact person/Author	Yin Li
Date prepared	August 28, 2026
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
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	Corvocet Biopsy System (K180450)

1. Device description

Automatic Core Biopsy Instrument is intended for use in obtaining biopsies from soft tissues. It has one model BN-OCR-13, and this model has two specifications: BN-OCR-13/xxyy and BN-OCR-13/xxyy/I. Specification BN-OCR-13/xxyy contains one biopsy instrument, and specification BN-OCR-13/xxyy/I contains one biopsy instrument and one coaxial biopsy needle.

Biopsy instrument of Automatic Core Biopsy Instrument is consisted of Inner stylet, Sampling cannula, Cutting cannula, Adjustable knob, Security lock, Button, Handle and Protective sheath.

Coaxial biopsy needle (internal code: CBN) of Automatic Core Biopsy Instrument is consisted of Inner Stylet, Cutting Cannula, Operating Handle of Cutting Cannula, Operating Handle of Inner Stylet, Blunt Needle (optional), Depth Stopper, and Protective Sheath. It is designed as guiding needle for Automatic Core Biopsy Instrument. The Cutting Cannula of coaxial biopsy needle is one gauge-size larger than the biopsy instrument, e.g., 19 gauge coaxial biopsy needle for a 20 gauge biopsy instrument.

2. Indications for use

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

3. Technological characteristics and product feature comparison

The following characteristics of subject device and predicate device are considered as substantially equivalent:

- Indications for use
- Operation mechanics
- Sterilization method
- Body contact sites
- Penetration depth

Comparison table

Comparison Items	**Subject Device**	**Predicate Device**	**Comment**
	Automatic Core Biopsy Instrument	**Corvocet Biopsy System**	
Indications for use	Automatic Core Biopsy Instrument is intended for use in obtaining biopsies from soft tissues such	The disposable Corvocet Biopsy System is intended for use in obtaining core biopsy samples from	Same

Comparison Items	Subject Device	Predicate Device	Comment
	Automatic Core Biopsy Instrument	Corvocet Biopsy System	
	as liver, kidney, prostate, spleen, breast, lung, lymph nodes and various soft tissue tumors. It is not intended for use in bone.	soft tissues such as liver, kidney, prostate, spleen, breast, lung, lymph nodes and various soft tissue tumors. It is not intended for use in bone.	
Operation mechanics	Automatic activation	Automatic activation	Same
Body contact site	Liver, kidney, prostate, spleen, breast, lung, lymph nodes and various soft tissue tumors.	Liver, kidney, prostate, spleen, breast, lung, lymph nodes and various soft tissue tumors.	Same
Nominal length of Cutting Cannula	8cm, 10cm, 13cm, 16cm, 20cm, 25cm	10cm, 15cm, 20cm, 25 cm	Different
Gauge size	14G, 16G, 18G, 20G	14G, 16G, 18G, 20G	Same
Penetration depth	10~25mm	10~25mm	Same
Sterilization method	EO sterilization	EO sterilization	Same

Difference in nominal length of cutting cannula:

The nominal length range of predicate device is from 10cm to 25cm, whereas that of the subject device ranges from 8cm to 25cm. Considering different lesion depths, 8cm is provided by subject device. Besides, given the same needle gauge, a longer needle is more susceptible to fracture. A shorter length presents a lower risk of breakage. This difference does not cause risks of safety or effectiveness.

4. Performance data

The following design verification and validation were performed to demonstrate the substantial equivalence of the subject device to the predicate device.

4.1 Biocompatibility testing

Biocompatibility testing was conducted in accordance with FDA guidance document, “Use of International Standard ISO 10993-1, “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” ” and

demonstrates that the product meets biological safety requirements for externally communicating medical devices with tissue contact for less than 24 hours.

- In Vitro Cytotoxicity Test (ISO 10993-5: 2009)
- Intracutaneous Reactivity Test (ISO 10993-23: 2021)
- Skin Sensitization test (ISO 10993-10: 2021)
- 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 able to maintain the sterility and performances of the product during its claimed shelf life. The testing is carried out in accordance with ASTM F1980-21.

4.4 Simulated transportation

Simulated transportation testing is conducted in accordance with ASTM D 4169. Test results indicate that product packaging can protect products from damage during transportation. Product packaging is sufficient enough to maintain the sterility and product performances during transportation.

4.5 Performance comparison with predicate devices

Comparison test was conducted between the subject device and predicate device 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 is provided.

6. Conclusion

Based on the device comparison and results of nonclinical testings, the subject device is substantially equivalent to the predicate device. The subject device incorporates comparable technological characteristics, demonstrate equivalent safety and performance, and does not raise new questions of safety or effectiveness.