January 24, 2025

Zhejiang CuraWay Medical Technology Co., Ltd.
Caili Cao
RA Specialist
Room 106, Building 1, No. 600 21st Avenue,
Baiyang Sub-district, Qiantang New District
Hangzhou, Zhejiang 310018
China

Re: K242322
Trade/Device Name: Bone Marrow 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 Caili Cao:

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.

Submission Number *(if known)*

K242322

Device Name

Bone Marrow Biopsy Needle (BNMAB-1, BNMA/CB-1)

Indications for Use *(Describe)*

The product is indicated for use in aspirating bone marrow and for use in obtaining core biopsy samples of bone and/or bone marrow.

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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510(K) Summary
K242322

Company Name/Owner	Zhejiang CuraWay Medical Technology Co., Ltd.
Contact person/Author	Caili Cao
Date prepared	December 9, 2024
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 Common	Bone Marrow Biopsy Needle
name Classification	Gastroenterology-urology biopsy instrument
name Review panel	Gastroenterology/Urology
Regulation number	21 CFR 876.1075
Product code	KNW
Predicate device	Jamshidi Evolve Bone Marrow Biopsy/Aspiration Needle (K171531)

1. Device Description

This product is a manual, sterile and disposable biopsy needle intended to aspirate bone marrow and obtain core biopsy samples of bone and/or bone marrow. The product is available in two models, BNMAB-1 and BNMA/CB-1. The main body of product consists of stylet part and cannula part, with a depth guard that can be adjusted for puncture depth. The model BNMA/CB-1 is equipped with an extraction cannula and extraction probe, they can be inserted into the cannula assembly to assist in cutting and removing the sample. The stylet part consists of the stylet and stylet socket, and the cannula part consists of the cannula and cannula socket. The cannula socket has a universal luer connector that can be used to connect the syringe and aspiration.

The stylet and cannula are combined to penetrate into the biopsy tissue, withdrawing the stylet and pushing the cannula forward into the tissue, at the mean time the bone tissue is extracted into the cannula lumen, swing the cannula to cut the root of the specimen, a full bone tissue is obtained.

The Bone Marrow Biopsy Needle is a single-use device, supplied in a sterile state sterilized by EO gas. Re-sterilization by users is forbidden. The shelf life is defined for 3 years.

2. Indications for use

The product is indicated for use in aspirating bone marrow and for use in obtaining core biopsy samples of bone and/or bone marrow.

3. Substantial equivalence comparison with predicate device

Jamshidi Evolve Bone Marrow Biopsy/Aspiration Needle (K171531) is selected as a predicate device to the subject Bone Marrow Biopsy Needle.

The subject device and predicate device are based on the same technological elements and intended use. There are several design differences, but do not cause a risk to the safety and effectiveness of the product, instead, such differences make it easier for users to operate the device. Detailed information please refer to comparison table below.

Comparison Elements	Subject Device	Predicate Device	Comment
	Bone Marrow Biopsy Needle	**Jamshidi Evolve Bone Marrow Biopsy/Aspiration Needle**	
Classification Regulation	876.1075	876.1075	Same
Product Code	KNW	KNW	Same
510(k) Number	K242322	K171531	/
Indications for use	The product is indicated for use in aspirating bone marrow and for use in obtaining core biopsy samples of bone and/or bone marrow.	Indicated for use in aspirating bone marrow and for use in obtaining core biopsy samples of bone and/or bone marrow.	Same
Operation mechanics	Manual	Manual	Same
Overall Product Design	Sterile, single-use, disposable	Sterile, single-use, disposable	Same
Patient/Tissue Contact Materials	Stainless steel and plastic	Stainless steel and plastic	Same
Contact site	Bone and bone marrow	Bone and bone marrow	Same
Biocompatibility	ISO 10093-1, ISO 10993-5, ISO 10993-10, ISO 10993-11, and ISO 10993-23	ISO 10093-1, ISO 10993-4, ISO 10993-5, ISO 10993-10 and ISO 10993-11	Difference 1
Sizes	9G, 11G, 13G, 14G, 15G, 16G, 18G	8G, 11G, 13G	Difference 2
Needle length (mm)	25, 40, 55, 70, 100, 150	50, 89, 100, 150, 200	Difference 3
Cannula Configuration	304 stainless steel hollow cannula	304 stainless steel hollow cannula	Same
Stylet Configuration	Solid stainless steel wire with three-edge	Solid stainless steel wire with two-edge	Difference 4

Comparison Elements	Subject Device	Predicate Device	Comment
	Bone Marrow Biopsy Needle	**Jamshidi Evolve Bone Marrow Biopsy/Aspiration Needle**	
Handle Configuration	Plastic handle on cannula	Plastic handle on cannula	Same
Bone Marrow Extraction Accessories	Extraction probe, probe guide, cap, some versions are provided with a extraction cannula.	Probe, probe guide, cap, some versions are provided with a specimen cradle.	Same (The components are translated into different words.)
Sterilization method	EO sterilization	EO sterilization	Same

4. Analysis of differences

Difference 1: Difference of biocompatibility

According to Annex A of ISO10993-1:2018, the Bone Marrow Biopsy Needle is an externally communicating medical device, contact with bone or bone barrow with less than 24 hours. Based on ISO 10093-1, the cytotoxicity, sensitization, irritation, acute systemic toxicity and pyrogen test could be the evaluation endpoint.

Difference 2: Difference of needle size

The needle size of the subject device is from 9G to 18G, and the needle size of predicate device is 8G to13G, the sizes of subject device 9G-13G are within the predicate device's, it is safe. For the 14G - 18G needles, Curaway has conducted in-vitro test use the worse case 18G needle, test results showed that the sampling performance can meet its intended purpose. The needle size difference does not cause new risks to device safety and effectiveness.

Difference 3: Difference of needle length

The length range of the subject product is 25 mm to 150 mm, while the predicate device's length range is 50 mm to 200 mm. Under the condition the diameter of the needle is certain, the long needles can penetrate deeper than short needles and cause more damage to the patient, therefore the short needles are safer than the long needles. Therefore, the needle length of 25mm and 40mm are not raise more safety risks than the length of 50mm.

Difference 4: Difference of stylet configuration

The stylet tip of subject device is a three-edge structure, the predicate device is a two-edge stylet. The material is same but design is different. Three-edge needle is a common type of needle, it has a special needle body structure like an arrow head with three sharp edges. Three-edge needles are widespread use in medicine, it has a sharp tip can improve the cutting efficiency. This design difference does not raise any new or significant questions of safety or effectiveness.

5. Non-Clinical Testing

The following testing was conducted to demonstrate the safe and effective use of subject devices and the standards that subject devices complied with:

- Packaging and shelf-life testing per ASTM F1980: 2016.
- Biocompatibility evaluation per ISO 10993-1: 2018, ISO 10993-5: 2009, ISO 10993-10: 2021, ISO 10993-11: 2017, and ISO 10993-23: 2021.
- Sterilization validation per ISO 11135: 2014, ISO 11138-1: 2017.
- EO Residuals testing per ISO 10993-7: 2008.
- Sterility testing per ISO 11737-2: 2019.

Bench tests (puncture test, torque test, stiffness test, toughness test and corrosion resistance test) were conducted on the subject Bone Marrow Biopsy Needle, all test results meet the performance requirements. Comparison test, including *ex vivo* sample quality comparison on the subject device and predicate device was conducted and all the result shows the subject are substantially equivalent to the predicate devices.

6. Clinical data

No clinical data was provided.

7. 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.