July 22, 2025

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

Re: K244018
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: December 27, 2024
Received: December 27, 2024

Dear Tu Mengjing:

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)*
K244018

Device Name
Disposable Biopsy Needle

Indications for Use *(Describe)*
Disposable Biopsy Needle is intended for use in soft tissue biopsies such as liver, kidney, breast, thyroid, prostate, spleen, pancreas, lymph nodes, lung and various soft tissue tumors. 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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510(K) Summary

K244018

Company Name/Owner	Zhejiang CuraWay Medical Technology Co., Ltd.
Contact person/Author	Mengjing Tu Telephone number: +86-0571-87016876
Date prepared	April 10, 2025
Contact details Address	Room 106, Building 1, No. 600, 21st Avenue, Baiyang Sub-district, Qiantang New District, 310018 Hangzhou City, Zhejiang Province, China
Trade name	Disposable Biopsy Needle
Common name	Biopsy Needle
Classification name	Instrument, Biopsy
Review panel	Gastroenterology/Urology
Regulation number	21 CFR 876.1075
Product code	KNW
Predicate device	**Pan® Aspirating Needle (Chiba)** (K970872) **Promisemed Fine Biopsy Needle** (K213683)

1. Device Description

Disposable Biopsy Needle is intended for use in obtaining an aspirate for cytology. Disposable Biopsy Needle has five models: BN-MAR-1, BN-MAR-2, BN-MAR-3, BN-MAR-4, BN-MAR-8.

The Disposable Biopsy Needle consists of operating handle of Inner stylet, operating handle of cutting cannula, cutting cannula, inner stylet, depth stopper and protective sheath.

The models differ as follows:

- ***Cutting cannula tip type:*** The cannula tip type of BN-MAR-1, BN-MAR-2, BN-MAR-3 is chiba. The cannula tip type of BN-MAR-4, BN-MAR-8 is greene.
- ***Operating handle designs:***

  BN-MAR-1, BN-MAR-3, BN-MAR-4 Models:

  a. BN-MAR-1, BN-MAR-3, and BN-MAR-4 have the same operating handle, including the operating handle of inner stylet and operating handle of cutting cannula.
  b. The Operating handle of Inner stylet connector connects to the Operating handle of cutting cannula connector via a straight snap-fit design, allowing for easy disconnection with one hand to remove the Inner stylet.

  BN-MAR-2, BN-MAR-8 Models:

  a. The Operating handle of Inner stylet of BN-MAR-2 connects to the Operating handle of cutting cannula via a straight snap-fit design connector, allowing easy disconnection with one hand to remove the Inner stylet.

  b. The Operating handle of inner stylet of BN-MAR-8 connects to the Operating handle of cutting cannula via a female Luer taper and male Luer thread taper, which can meet the sealing performances in clinical applications.

- ***Bevel Angle of the Cutting cannula tip:*** There are three kinds of bevel angle of the Cutting cannula tip, which are α, β, δ. The bevel angle of the cutting cannula tip of BN-MAR-1 and BN-MAR-2 is α. The bevel angle of the needle tip of BN-MAR-3 is β. The bevel angle of the Cutting cannula tip of BN-MAR-4 and BN-MAR-8 is δ.

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

The cutting cannula has numerically ordered centimeter markings 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.

An adjustable depth stopper allows the user to restrict forward movement, localizing the needle tip to the biopsy site.

The Operating handle of Inner stylet is color-coded, which indicates gauge size of the needle. It is available in several needle gauge sizes and lengths.

The Disposable 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, which is verified.

2. Intended use / Indications

Intended use:

Disposable Biopsy Needle is intended for use in obtaining an aspirate for cytology.

Indications:

Disposable Biopsy Needle is intended for use in soft tissue biopsies such as liver, kidney, breast, thyroid, prostate, spleen, pancreas, lymph nodes , lung and various soft tissue tumors. 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 devices.

Pan® Aspirating Needle (Chiba) (K970872) and Promisemed Fine Biopsy Needle (K213683) were selected as predicate devices to the Disposable Biopsy Needle (Subject device).

The subject device and predicate devices 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. Detailed information please refer to comparison table below. Please refer to the following Table 1 for details.

Table 1: Substantial equivalence comparison of Disposable Biopsy Needle

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Comment
Proprietary Name	Disposable Biopsy Needle	Pan® Aspirating Needle (Chiba)	Promisemed Fine Biopsy Needle	-
Classification Regulation	876.1075	876.1075	876.1075	Same
Product Code	KNW	KNW	KNW	Same
510(k) Number	K244018	K970872	K213683	-
Intended Use	Disposable Biopsy Needle is intended for use in obtaining an aspirate for cytology.	It is to be used for taking cytological and histological biopsies of soft tissue.	It is to be used for taking cytological and histological biopsies of soft tissue.	Same
Visualization technique	The introduction of the needle into the body should be carried out under imaging guidance (ultrasound, X-Ray, CT) .	It's a relatively invasive procedure and is performed by radiologist under guidance of imaging techniques such as ultrasound, X-ray.	It's a relatively invasive procedure and is performed by radiologist under guidance of imaging techniques such as ultrasound, X-ray.	Difference 1
Materials	-Cutting cannula and Inner stylet: Stainless Steel (SUS304) -Operating handle of cutting cannula, Operating handle of inner stylet: Polycarbonate (PC) - Depth stopper: Thermoplastic Elastomer (TPE)	- Needle: Stainless Steel (X5CrNi18-10); - Needle base: Acrylonitrile Butadiene Styrene (ABS) - Depth stop: Thermoplastic Elastomer (TPE)	- Needle: Stainless Steel (X5CrNi18-10); - Needle base: Acrylonitrile Butadiene Styrene (ABS) - Depth stop: Thermoplastic Elastomer (TPE)	Difference 2

<table>
<tr><th>Comparison Elements</th><th>Subject Device</th><th>Predicate Device 1</th><th>Predicate Device 2</th><th>Comment</th></tr>
<tr><td>Single use</td><td>YES</td><td>YES</td><td>YES</td><td>Same</td></tr>
<tr><td>Needle Hub</td><td>Luer hub</td><td>Luer hub</td><td>Luer hub</td><td>Same</td></tr>
<tr><td colspan="5">Performance</td></tr>
<tr><td>Echogenic</td><td>YES</td><td>YES</td><td>YES</td><td>Same</td></tr>
<tr><td>Connector transparency</td><td>Transparent/lock</td><td>Transparent/lock</td><td>Transparent/lock</td><td>Same</td></tr>
<tr><td>Needle Gauge</td><td>16G, 17G, 18G, 19G, 20G, 21G, 22, 23G, 24G, 25G</td><td>18G, 20G, 21G, 22G, 23G, 25G</td><td>16G, 18G, 19G, 20G, 21G, 22G, 23G</td><td>Difference 3</td></tr>
<tr><td>Needle Length</td><td>40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 210, 220, 230, 240, 250 mm</td><td>50, 80, 90, 150, 200 mm</td><td>90mm, 100mm, 150mm, 200mm</td><td>Difference 4</td></tr>
<tr><td>Needle tube tip type</td><td>Chiba, Greene</td><td>Chiba</td><td>Chiba</td><td>Difference 5</td></tr>
<tr><td>Bond between outer needle tube and hub</td><td>according to the nominal OD of the outer needle, the outer needle and hub shall not break when pull the needle with the axial static force specified in the below table for 10s.<table><tr><td>OD</td><td>Force/N</td></tr><tr><td>23G</td><td>34</td></tr></table></td><td>according to the nominal OD of the outer needle, the outer needle and hub shall not break when pull the needle with the axial static force specified in the below table for 10s.<table><tr><td>OD</td><td>Force/N</td></tr><tr><td>23G</td><td>34</td></tr></table></td><td>according to the nominal OD of the outer needle, the outer needle and hub shall not break when pull the needle with the axial static force specified in the below table for 10s.<table><tr><td>OD</td><td>Force/N</td></tr><tr><td>23G</td><td>34</td></tr></table></td><td>Same</td></tr>
<tr><td>Biocompatibility</td><td>ISO 10993 series standards</td><td>ISO 10993 series standards</td><td>ISO 10993 series standards</td><td>Same</td></tr>
<tr><td>Anatomical</td><td>Soft tissue biopsies such as liver,</td><td>Soft tissue</td><td>Soft tissue</td><td>Difference 6</td></tr>
</table>

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Comment
sites	kidney, breast, thyroid, prostate, spleen, pancreas, lymph nodes , lung and various soft tissue tumors. It is not intended for use in bone.			
Sterilization method	EO sterilization	EO sterilization	EO sterilization	Same

Difference 1: Visualization technique

The difference between the Subject device and the predicate device is the subject device not imaging under the CT. The usability of the subject device under CT has been verified.

Difference 2: Materials

The difference between the Subject device and the predicate device is the PC material. PC do not come into contact with patients, so it will not bring safety risks

Difference 3: Needle Gauge

Subject device has two gauge sizes (17G, 24G) more than predicate devices. The 17G OD and 24G OD of Cutting cannula of subject device are within the predicate devices'. It will not cause new risks to device safety and effectiveness.

Difference 4: Needle Length

It can be seen from the table above that subject device provides more selections on the Length of Cutting Cannula, namely 40mm, 60mm, 70mm,

110mm, 120mm, 130mm, 140mm, 160mm, 170mm, 180mm, 190mm, 210mm, 220mm, 230mm, 240mm, 250 mm. The 60mm, 70mm, 110mm, 120mm, 130mm, 140mm, 160mm, 170mm, 180mm, 190mm are within the length range (50mm to 200mm) of predicate devices. Besides, considering the different shape of patients and the distance between needle insertion point and lesion, 40mm, 210mm, 220mm, 230mm, 240mm and 250mm are provided by subject device. The puncture length is judged by the clinician, and we offer a wider selection of puncture lengths that do not raise new issues affecting the safety and effectiveness of the devices. The additional puncture lengths are similar to other marketed products with the same intended use.

Difference 5: Cutting Cannula tip type

The puncture process: The Chiba type has a blade on the tip of Cutting cannula for puncture, while the Greene type has a blade on the tip of Inner stylet, but both use a combination of the Cutting cannula and Inner stylet to achieve puncture, and the process is the same.

The sampling process: When sampling with the Chiba type, the Inner stylet is withdrawn, and only the Cutting cannula is operated to take a sample at the lesion site. The tip of Cutting cannula can move back and forth with the operator's technique, but high demands are placed on the operator's technique to avoid damaging the tissue around the needle. When sampling with the Greene type, the Inner stylet is withdrawn, and only the Cutting cannula is operated to take a sample at the lesion site. The tip of Cutting cannula is flat and dull, and it is not easy to move back and forth with the operator’s technique. Despite this difference in design, performance testing in the indicated tissue types demonstrated substantially equivalent safety and effectiveness.

Difference 6: Anatomical sites

Though the indications for use descriptions are not identical, the specific indications designating anatomical sites are within the same intended use as the predicate and do not raise different questions of safety and effectiveness.

Based on the risk analysis of the above differences, the differences do not affect the safety and effectiveness of the equipment.

4. Non-Clinical Tests

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.
- Biocompatibility evaluation per ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11 and ISO 10993-23.
- Sterilization validation per ISO 11135: 2014.
- EO Residuals testing per ISO 10993-7: 2008.
- Performance testing including Appearance, Basic dimensions, Sample collection space and accessibility, Luer connection, Connection firmness, Stiffness, Toughness, Corrosion resistance, Leakage, Ultrasound detectability, X-ray detectability, Protective sheath, Puncture force, Chemical Characteristics, EO and ECH Residual, Sterility test, Bacterial endotoxin.
- A comparative study was conducted between CuraWay's Disposable Biopsy Needle and the predicate devices across various tissues including liver, kidney, breast, thyroid, prostate, spleen, pancreas, lymph nodes, and lungs. The results showed no significant difference in sampling weight or cell integrity between the subject and predicate devices.

5. Clinical data

No clinical data was provided.

6. Conclusion

The indications for use of subject device are equivalent to the predicate device. The standards testing and nonclinical performance testing demonstrate that the subject device technological characteristics are equivalent to the predicate device for biopsy of soft tissue. In conclusion, the subject device is substantially equivalent to the predicate devices.