May 22, 2023

YouCare Technology Co., Ltd. (Wuhan)
Bing Hu
Manager
Great Wall Science and Technology Park
East Lake Development Zone, Wuhan
Wuhan,
China

Re: K222705
Trade/Device Name: Introducer Needle
Regulatory Class: Unclassified
Product Code: LJE
Dated: May 9, 2023
Received: May 10, 2023

Dear Bing Hu:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.05.22 11:37:24 -04'00'

Mark Trumbore, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Introducer Needle

Indications for Use *(Describe)*
It is used for percutaneous puncture to the renal pelvis, establishing a percutaneous approach and providing working access for endoscopes and surgical instruments.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

YouCare Technology Co., Ltd.(Wuhan).

Section 5 - 510(k) Summary

Date of Summary Preparation: 08/29/2022

1. Submitter's Identifications

Submitter's Name: YouCare Technology Co., Ltd.(Wuhan).
Address: Great Wall Science and Technology Park, East Lake Development Zone Wuhan.

Contact Person: Bing Hu
Contact Email: hb@youcaretech.com
Telephone: 86-027-87926396-830

2. Correspondent's Identifications

Correspondent's Name: YouCare Technology Co., Ltd.(Wuhan).
Address: Great Wall Science and Technology Park, East Lake Development Zone Wuhan.
Contact Person: Bing Hu
Contact Email: hb@youcaretech.com
Telephone: 86-027-87926396-830

3. Name of the Device

Product Name: Introducer Needle
Trade Name: Introducer Needle
Model:
YC-Jianxing-needleperc-A
YC-Jianxing-needleperc-B
YC-Jianxing-needleperc-C.
(Other places in the document are abbreviated as Model A, Model B, Model C)
Classification Panel: Gastroenterology/Urology
Product Code: LJE
Device Classification: Unclassified

4. The Predicate Devices

K183035

Percutaneous Entry Set

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

5. Device Description

The product consists of a needle tube, a needle hub, a rear end, equipment channel interface E, fiber image channel interface F, irrigation channel interface I, an obturator, a needle-free joint and a two-way water valve, and that primary package of the product

contains a protective sleeve which is only used for product protection. The product is sterilized by ethylene oxide and is single use.

6. Intended Use

It is used for percutaneous puncture to the renal pelvis, establishing a percutaneous approach and providing working access for endoscopes and surgical instruments.

7. Comparison to Predicate Device

<table>
<tr><th></th><th>New device</th><th>Predicate device</th><th>Comparison</th></tr>
<tr><td>“K”NUMBERS</td><td>/</td><td>K183035</td><td>/</td></tr>
<tr><td>Manufacturer</td><td>YouCare Technology Co., Ltd.(Wuhan).</td><td>Cook Incorporated</td><td>/</td></tr>
<tr><td>Product Code</td><td>LJE</td><td>LJE</td><td>Same</td></tr>
<tr><td>Classification name</td><td>Gastroenterology/Urology</td><td>Gastroenterology/Urology</td><td>Same</td></tr>
<tr><td>Intended Use</td><td>It is used for percutaneous puncture to the renal pelvis, establishing a percutaneous approach and providing working access for endoscopes and surgical instruments.</td><td>The Percutaneous Entry Set is used to establish percutaneous tract into the renal pelvis for catheter placement or stone manipulation.</td><td>Same</td></tr>
<tr><td>Regulatory Class</td><td>Unclassified</td><td>Unclassified</td><td>/</td></tr>
<tr><td>Sterility</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td>Sterilization Method</td><td>EO</td><td>EO</td><td>Same</td></tr>
<tr><td>Single Use</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td>Lengths/Sizes</td><td>
<table>
<tr><td></td><td>Model A</td><td>Model B</td><td>Model C</td></tr>
<tr><td>Needle Gauge</td><td>17 Ga</td><td>17 Ga</td><td>14 Ga</td></tr>
<tr><td>Diameter</td><td>4.2 Fr</td><td>4.5 Fr</td><td>6.0 Fr</td></tr>
<tr><td>Needle Length/ Introducer length</td><td colspan="3">152mm±7mm</td></tr>
<tr><td>Total length</td><td colspan="3">263mm±7mm</td></tr>
</table>
</td><td>Needle Gauge: 18
Needle Length: 15-20cm</td><td>Different 1</td></tr>
</table>

<table>
<tr><td>Primary structure</td><td>Needle tube and rear end with three channels
  </td><td>The Percutaneous Entry Set is comprised of a Skinny Needle® with Chiba Tip, a Disposable Two-Part Trocar Needle, 8 dilators and a wire guide.</td><td>Different 2</td></tr>
<tr><td>Materials</td><td>
<table>
<tr><td>Needle tube</td><td>304 Stainless Steel</td></tr>
<tr><td>needle hub</td><td rowspan="2">ABS</td></tr>
<tr><td>rear end</td></tr>
<tr><td>equipment channel interface E</td><td rowspan="3">polycarbonate（PC）</td></tr>
<tr><td>fiber image channel interface F</td></tr>
<tr><td>irrigation channel interface I</td></tr>
<tr><td>needle-free joint</td><td>polycarbonate（PC）、silica gel</td></tr>
<tr><td>obturator</td><td>polycarbonate（PC）、silica gel</td></tr>
<tr><td>two-way water valve</td><td>polycarbonate（PC）、Polyoxymethylene</td></tr>
</table>
</td><td>Needle: 304 Stainless Steel</td><td>Different 3</td></tr>
<tr><td>Mode of Operation</td><td>Manual Insertion</td><td>Manual Insertion</td><td>Same</td></tr>
<tr><td>usage method</td><td>Needle tube as instrumental channel</td><td>Needle tube as instrumental channel</td><td>Same</td></tr>
<tr><td>Requirements</td><td>flow test
penetration force
Stiffness
Resistance to breakage
Bond between hub and needle tube
ultrasound detection
Corrosion Test</td><td>flow test
penetration force
Stiffness
Resistance to breakage
Bond between hub and needle tube
ultrasound detection
Corrosion Test</td><td>Same</td></tr>
<tr><td>Biocompatible</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td>Shelf Life</td><td>2 years</td><td>3 years</td><td>Different 4</td></tr>
</table>

8. Substantial equivalence discussion:

Different 1 - **Lengths/Sizes**

This difference is in diameter and length. Different diameter device will be selected by physician per patient's condition. Moreover, a small diameter difference has little effect on the product safety performance; For different length, B-ultrasonic and endoscopic double positioning was used at the time of surgery, the length difference did not affect the safety and efficacy of the product.

Different 2 - **Primary structure**

The Percutaneous Entry Set is comprised of a Skinny Needle® with Chiba Tip, a Disposable Two-Part Trocar Needle, 8 dilators and a wire guide. The function and structure of new device is similar to **Disposable Two-Part Trocar Needle** of Percutaneous Entry Set. The reasons are:

1. Disposable Two Part Trocar Needle has a trocar tip, which is used for free flow of urine indicators proper positioning. Our product can be used in conjunction with a fiber optic endoscope during puncture to achieve visual puncture and directly see whether the puncture has reached the expected position. it does not raise different questions of safety and effectiveness for patient, it only increases the operation requirements for doctors

2. New device does not have a trocar tip, but we have conducted Stiffness and Resistance to breakage tests to ensure that the needle tube will not break without a trocar tip, so it will not be affected by safety and effectiveness.

Different 3 - **Materials**

The materials of direct contacting component puncture body are different. The new device is 304 Stainless Steel, materials of predicate device are 304 Stainless Steel and Low-Density Polyethylene; The materials of indirect tissue-contacting components are different, but the whole device passed the biological test.

Different 4 - **Shelf Life**

The difference in shelf life does not affect the product.

Substantial Equivalence discussion:

The subject devices have similar indications for use, methods of operation, and fundamental technological characteristics as the predicate device. Differences between the subject devices and the predicate device include design specifications, dimensions, and materials. Characteristics of the subject devices that differ from the predicate device are supported by testing.

9. Performance Data:

The following performance data were provided in support of the substantial equivalence determination.

9.1 Biocompatibility testing

The biocompatibility evaluation for the Introducer Needle was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

Skin Sensitization
Intracutaneous Reactivity
Acute Systemic Toxicity

Pyrogen

9.2 Physical and chemical performance testing. Performance testing was performed in accordance with applicable clauses in ISO 9626-2016 and ISO 7864-2016， The following testing was performed to demonstrate that the Introducer Needle met applicable design requirements.

flow test
penetration force
Stiffness
Resistance to breakage
Bond between hub and needle tube
ultrasound detection
Corrosion Test

9.3 Packaging and shelf-life testing

Sterilization
Packaging
Shelf-life

10. Conclusion:

The results of these tests provide reasonable assurance that the Introducer Needle will perform as intended. The new devices do not raise new questions of safety or effectiveness as compared to the predicate device. In conclusion, the results of these tests support a determination of substantial equivalence to the predicate device.

--- End of this section ---