September 12, 2023

Jiangsu Vedkang Medical Science and TechnologyCo., Ltd.
Qian Wen, RA
No.52, Guoxiang Road, Wujin Economic Development Zone
Changzhou, Jiangsu 213149
China

Re: K230598
Trade/Device Name: Stone Extraction Baskets
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: LQR
Dated: August 14, 2023
Received: August 15, 2023

Dear Qian Wen:

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,

Glenn B. Bell -S

Glenn B. Bell, PhD
Division Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K230598

Device Name
Stone Extraction Baskets

Indications for Use *(Describe)*
Endoscopic removal of stones in the biliary system and foreign bodies.

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.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

1. Date of Preparation: 08/31/2023

2. Sponsor Identification

Jiangsu Vedkang Medical Science and Technology Co., Ltd.
No.52, Guoxiang Road, Wujin Economic Development Zone, Changzhou 213149, Jiangsu, P.R. China

Establishment Registration Number: 3013526170

Contact Person: Qian Wen
Position: RA
Tel: +86-519-69877791-8147
Email: info@vedkang.com

3. Designated Submission Correspondent

Ms. Qian Wen (Primary Contact Person)
Ms. Zhang Lin (Alternative Contact Person)

Jiangsu Vedkang Medical Science and Technology Co., Ltd.
No.52, Guoxiang Road, Wujin Economic Development Zone, Changzhou 213149, Jiangsu, P.R. China

Tel: +86-519-69877757
Email: info@vedkang.com

4. Device

Trade Name: VedBasket, Stone Extraction Baskets
Common Name: Stone Extraction Baskets

Regulatory Information
Classification Name: Biliary Catheter and Accessories
Classification: II;
Product Code: LQR
Regulation Number: 21 CFR 876.5010
Review Panel: Gastroenterology/Urology

Indication for use:
Endoscopic removal of stones in the biliary system and foreign bodies.

Device Description

The Stone Extraction Baskets is a sterile, single use device compatible with the accessory channel of endoscopes (Minimum Endoscope Channel Inner Diameter: 2mm and 2.8mm).
Diameters of Outer Tube of the device are 1.8mm and 2.3mm, working lengths are 700mm,1200mm,2000mm and 2300mm, and open widths are 10mm, 15mm, 20mm,25mm,30mm,35mm,40mm, and the devices have eight types of baskets and two kinds of handles (single hand type and two hands type).
It is comprised of guiding head (stainless steel), basket (stainless steel/nitinol), pulling wire (stainless steel), outer tube(PTFE) and handle components (ABS, stainless steel and etc.). Basket is advanced out of and retracted into the polytetrafluoroethylene outer tube using the handle component's rear handle. The device is not compatible with any mechanical lithotripter.

5. Predicate Device

510(k) Number: K171969
Trade Name: Web II Memory Extraction Basket or Memory II Double Lumen Extraction Basket, Memory 5 Fr. Soft Wire Baskets or Memory Helical Stone Extractor, Memory Eight Wire Baskets or Memory Hard Wire Baskets, Fusion Wire Guided Extraction Basket, Non-Lithotripsy Extraction Basket
Common Name: Dislodger, Stone, Biliary

6. Performance Data and Non-Clinical Test Conclusion

Performance testing consisting of sterilization, shelf life, biocompatibility, and nonclinical bench testing demonstrate that the Stone Extraction Basket meets the performance criteria required to fulfill the intended use of the device. The following summarizes the non-clinical bench testing conducted:

- Endoscope insertion removal durability test
- Dimension test
- Tensile strength test
- Operational performance test (Flexibility Testing included)
- Stone and Foreign Body Capture Test

7. Substantially Equivalent (SE) Comparison

Our proposed device Stone Extraction Basket is substantially equivalent to the predicate devices. The differences between the Stone Extraction Basket and the predicate devices do not raise any questions regarding its safety and effectiveness. The differences are listed in the table below:

ITEM	Proposed Device	Predicate Device K171969	Remark
Common name	Stone Extraction Baskets	Dislodger, Stone, Biliary	/
Trade Name	VedBasket, Stone Extraction Baskets	Web II Memory Extraction Basket or Memory II Double Lumen Extraction Basket, Memory 5 Fr. Soft Wire Baskets or Memory Helical Stone Extractor, Memory Eight Wire Baskets or Memory Hard Wire Baskets, Fusion Wire Guided Extraction Basket, Non-Lithotripsy Extraction Basket	/
Indication for Use	Endoscopic removal of stones in the biliary system and foreign bodies.	Endoscopic removal of stones in the biliary system and foreign bodies.	Same
Environment of use	Hospital	Hospital	Same
Single Use	Single Use	Single Use	Same
Outer tube diameter	1.8mm,2.3mm	5.5Fr（≈1.83mm） 7.0 Fr（≈2.33mm）	Different
Minimum Accessory Channel	2.0mm, 2.8mm	2mm	Different
Open width	10mm,15mm,20mm,25mm,30mm,35mm,40mm	20mm, 30mm	Different
Handle type	Two handle type, Single handle type	Rotatable pin vise, two handle type.	Different
Sterilization			
Method	EO Sterilized	EO Sterilized	Same

Conclusion: The fundamental principle of operation for both the subject and predicate devices are the same. There are differences in the subject and predicate device technology - outer tube diameter, open widths, working lengths and handle types. These differences between the Stone Extraction Basket and the predicate device were evaluated utilizing performance testing and do not raise any questions regarding its safety and effectiveness.

8. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device, Stone Extraction Baskets, is determined to be Substantially Equivalent (SE) to the predicate device K171969.