February 26, 2024

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

Re: K232752
Trade/Device Name: Stone Extraction Balloon (VDK-BAL-23-11/13/15-B, VDK-BAL-23-15/18/20-B,VDK-BAL-23-9/12/15-B, VDK-BAL-23-10/13/16-B,VDK-BAL-23-8.5/11.5/15-B, VDK-BAL-23-12/15/18-B,VDK-BAL-23-11/13/15-C, VDK-BAL-23-15/18/20-C,VDK-BAL-23-9/12/15-C, VDK-BAL-23-10/13/16-C,VDK-BAL-23-8.5/11.5/15-C, VDK-BAL-23-12/15/18-C)
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: GCA
Dated: August 30, 2023
Received: September 8, 2023

Dear Zheng Xinxing:

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.

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,

Anthony Lee -S

Anthony C. Lee, Ph.D.
Assistant 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K232752

Device Name

Stone Extraction Balloon (VDK-BAL-23-11/13/15-B，VDK-BAL-23-15/18/20-B，VDK-BAL-23-9/12/15-B，VDK-BAL-23-10/13/16-B,VDK-BAL-23-8.5/11.5/15-B,VDK-BAL-23-12/15/18-B,VDK-BAL-23-11/13/15-C,VDK-BAL-23-15/18/20-C,VDK-BAL-23-9/12/15-C,VDK-BAL-23-10/13/16-C,VDK-BAL-23-8.5/11.5/15-C,VDK-BAL-23-12/15/18-C)

Indications for Use *(Describe)*

The device is intended for endoscopic removal of biliary stones. The device is supplied sterile and intended for single use only.

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.

The assigned 510(k) Number: K232752

1. Date of Preparation: 08/30/2023

2. Sponsor Identification

Jiangsu Vedkang Medical Science and Technology Co., Ltd.
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Ms. Xinxing Zheng Primary Contact Person)
Ms.Lin Zhang(Alternative Contact Person)

3. Proposed Device

Trade Name: Stone Extraction Balloon (VDK-BAL-23-11/13/15-B,VDK-BAL-23-15/18/20-B,VDK-BAL-23-9/12/15-B,VDK-BAL-23-10/13/16-B,VDK-BAL-23-8.5/11.5/15-B,VDK-BAL-23-12/15/18-B,VDK-BAL-23-11/13/15-C,VDK-BAL-23-15/18/20-C,VDK-BAL-23-9/12/15-C,VDK-BAL-23-10/13/16-C,VDK-BAL-23-8.5/11.5/15-C,VDK-BAL-23-12/15/18-C)

Common Name: Stone Extraction Balloon

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

Indication for use:

The device is intended for endoscopic removal of biliary stones. The device is supplied sterile and intended for single use only.

Device Description

Stone Extraction Balloon is composed of balloon, radiopaque marker, catheter, handle, standard connector, two-way valve, support wire and inflators. Stone Extraction Balloon is operated by the Inflators to control the inflation and deflation of balloon, as well as liquid is injected through the injection port to assist in imaging or flushing, and complete the removal of biliary calculus through the endoscopic channel. The Stone Extraction Balloon is classified to different specifications according to the diameter of balloon and the location of the liquid outlet. There are a total of 12 models, the largest balloon diameter is 20mm, the smallest balloon diameter is only 8.5mm, the operator can choose according to different clinical needs. EO sterilization and use for single use only.

4. Predicate Device

510(k) Number: K210660
Trade Name: Stone Retrieval Balloon Catheter
Common Name: Stone Retrieval Balloon Catheter

5. Performance Data and Non-Clinical Test Conclusion

Performance testing consisting of Size, Appearance, Maneuverability, Strength, Airtightnes, Ruhr cone, Sterility and EO Residual amount. Non-clinical bench testing demonstrate that the Stone Extraction Balloon meets the performance criteria required to fulfill the intended use of the device. The following summarizes the Non-clinical bench testing conducted:

- Stone capture testing
- Tensile strength test
- Operational performance test
- Dimension Test
- Luer Connector Test
- Flexibility testing

- X-Ray Development test
- Rated Burst Pressure test
- Flowrate test

The non-clinical performance meets the design specification and shows substantial equivalence to the predicated device.

6. Clinical Test Conclusion

No clinical study is included in this submission.

7. Substantially Equivalent (SE) Comparison

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

Device Characteristic	Proposed Device	Predicate Device K210660	Remark
Product	Stone Extraction Balloon	Stone Retrieval Balloon Catheter	/
Product Code	GCA	GCA	/
Regulation Number	21 CFR §876.5010	21 CFR §876.5010	/
Class	Class II	Class II	/
Indication for Use	The device is intended for endoscopic removal of biliary stones. The device is supplied sterile and intended for single use only	The device is intended for endoscopic removal of biliary stones. The device is supplied sterile and intended for single use only	Same
Environment of use	Hospital	Hospital	Same
Intended users	The device must be used by trained doctors or technicians.	The device must be used by trained doctors or technicians.	Same
Single Use	Single Use	Single Use	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Balloon Diameter	8.5mm/11.5mm/15mm、9mm/12mm/15mm、10mm/13mm/16mm、11mm/13mm/15mm、12mm/15mm/18mm、15mm/18mm/20mm	8.5/12/15/18/8.5-12-15/12-15-18	Different
Catheter Length	2000mm	2000mm	Same
Catheter diameter	2.3mm	2.3mm	Same
Lumens corresponds	a balloon inflation port, a wire guide port and an injection port	a balloon inflation port, a wire guide port and an injection port	Same

Guidewire Compatibility(in)	0.035/0.025	0.035/0.025	Same
Patient contact material	Balloon:Natural latex Radiopaque band:Ta Three internal lumens: Pebax; Binder:UV-curing adhensive;	Three internal lumens: Pebax; Radiopaque band: Ta; Bind wire: PET; Balloon: Natural latex; Binder: UV-curing adhensive; Marker: TPU ink.	Different
Bocompatibility	In Vitro Cytotoxicity Test : ISO 10993-5: 2009; Skin sensitization Test :ISO 10993-10: 2010; Intracutaneous Reactivity Test: ISO 10993-10: 2010.	In Vitro Cytotoxicity Test : ISO 10993-5: 2009; Skin sensitization Test :ISO 10993-10: 2010; Intracutaneous Reactivity Test: ISO 10993-10: 2010.	Same
Sterilization			
Method	EO Sterilized	EO Sterilized	Same

Different – Balloon Diameter

The working length for proposed device is different from the predicate device K210660. The different length will be selected by physician per patient's condition and this difference does not affect intended use. For the 20mm balloon, we provide the following support evidence to demonstrate that it will not raise different questions regarding its safety and effectiveness. First, we searched in the FDA 510k Premarket Notification database for other similar retrieval balloon catheter, and we found Olympus's 3-Lumen Extraction Balloon (K091495), maximum diameter of the balloon(mm) is 20mm, it is shown in the 510(k) summary: Second, there is a literature that retrieval balloon catheter is used to remove stones in the bile duct which the mean common bile duct (CBD) dilation was 19.2mm±3.9 and the mean size of stones 15.8±2.9.At least, the performance tests were conducted on proposed device and predicate device, and the test result does not show any significant difference. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different-Material

The patient contact material for the proposed device is different from the predicate device. However, biocompatibility test has been conducted on the proposed device and the test result does not show any adverse effect. Therefore, this difference will not raise any safety issues.

8. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device, Stone Extraction Balloon, is determined to be Substantially Equivalent (SE) to the predicate device K210660.