February 15, 2024

Jiangsu Vedkang Medical Science and Technology Co., Ltd.
Zhang Lin
Regulatory Affairs
No.52, Guoxiang Road, Wujin Economic Development Zone
Changzhou, Jiangsu 213149
China

Re: K232245
Trade/Device Name: VedDilator™
Common Name: 3-Stage Balloon Dilation Catheter
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE, KNQ
Dated: January 15, 2024
Received: January 16, 2024

Dear Zhang Lin:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232245

Device Name
VedDilator

Indications for Use *(Describe)*
It is indicated for use in adult and adolescent populations to endoscopically dilate or auxiliary dilate strictures of the alimentary tract.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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: K232245

1. Date of Preparation: 01/15/2024

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: Zhang Lin

Position: RA

Tel: +86-519-69877791-8147

Email:lin.zhang@vedkang.com

Ms. Zhang Lin (Primary Contact Person)

Ms. Chen Jie(Alternative Contact Person)

3. Proposed Device

Trade Name: VedDilator ™

Common Name: 3-Stage Balloon Dilation Catheter

Regulatory Information

Regulation Name: Biliary Catheter and Accessories

Classification:Class II;

Product Code: FGE, KNQ

Regulation Number: 21 CFR 876.5010

Review Panel: Gastroenterology/Urology

4. Predicate Device

510(k) Number: K112994

Trade Name: CRE Dilatation Balloon

Common Name: CRE Wireguided Dilatation Balloon

5. Indication for use:

It is indicated for use in adult and adolescent populations to endoscopically dilate or auxiliary dilate strictures of the alimentary tract.

Device Description

The 3-Stage Balloon Dilation Catheter can provide 3 different sizes and gradually increasing diameters through controlled radial expansion. The specific balloon size is printed on the label of each package and catheter. The 3-Stage Balloon Dilation Catheter is designed to pass through the working channel of the endoscope, and its guidewire cavity can accommodate a 0.035inches (0.89mm diameter) guidewire. In the package, a 0.035inches (0.89mm diameter) guidewire is pre-installed in the guidewire cavity. There is a guidewire locking device connected to the guide wire hole of the catheter. The locking device will be in the "OFF" (closed) position when it leaves the factory. Only when the switch of the locking device is in the "ON" position can it be pushed or moved forward. The guide wire is removed from the catheter. After turning the switch to the "OFF" position, the guide wire will be fixed in the catheter.

6. Performance Data and Non-Clinical Test Conclusion

Performance testing consisting of sterilization, shelf life, biocompatibility, and Non-clinical bench testing demonstrate that the 3-Stage Balloon Dilation Catheter meets the performance criteria required to fulfill the intended use of the device. The following summarizes the Non-clinical bench testing conducted:

- Rated burst pressure test
- Balloon tightness test
- Connection firmness test
- Maneuverability test
- X-ray development performance test
- Sterility test
- Residual amount of ethylene oxide Test
- Balloon fatigue Test
- Burst Test of Guidewire
- Bend Test of Guidewire
- Connection Strength Test of Guidewire
- Corrosion resistance Test of Guidewire

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

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Our proposed device 3-Stage Balloon Dilation Catheter is substantially equivalent to the predicate devices. The differences between the 3-Stage Balloon Dilation Catheter 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 K112994	Remark
Common name	3-Stage Balloon Dilation Catheter	CRE Wireguided Dilatation Balloon	/
Trade Name	VedDilator ™	CRE Dilatation Balloon	/
Product Code	FGE,KNQ	1) KOG, 2) KNQ, 3) FGE	Same
Regulation Number	21 CFR 876.5010,21 CFR 876.5365	1) 876.5010, 2) 876.5365, 3) 876.5010	Same
Class	Class II	Class II	Same
Indication for Use	It is indicated for use in adult and adolescent populations to endoscopically dilate or auxiliary dilate strictures of the alimentary tract.	The CRE™ Wireguided Balloon Dilatation Catheter is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. It is also indicated in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy.	Same
Configuration	balloon, radiopaque bands, catheter and three-way handle	balloon, radiopaque bands, catheter and three-way handle	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
Specifications			
guidewire lumen	0.035 in (0.89 mm)	0.035 in (0.89 mm)	Same
Minimum working channel	Endoscope:some models is 2.0 mm, some are 2.8 mm, and some are 3.2 mm	Endoscope:2.8mm Duodenoscope and Endoscope:3.2 or 4.2 mm	Different
Diameter of balloon (mm)	4/5/6、6/7/8、8/9/10、10/11/12、12/13.5/15、15/16.5/18、18/19/20	6/7/8、8/9/10、10/11/12、12/13.5/15、15/16.5/18、18/19/20	Different
Working Length (mm)	900、1200、1800、2000、2300	1800、2400	Different
Performance	Rated burst pressure test, Balloon tightness test,Connection firmness	Unknown	Different

	test,Maneuverability test,X-ray development performance test,Sterility test,Residual amount of ethylene oxide Test,Balloon fatigue Test,Burst Test of Guidewire,Bend Test of Guidewire, Connection Strength Test of Guidewire and Corrosion resistance Test of Guidewire;etc		
Biocompatibility			
Patient contact material	Guide head (PA) Balloon (Pebax) Catheter (PA) Guidewire (SUS304,PTFE)	Guide head (Pebax) Balloon (Pebax) Catheter (Pebax) Guidewire (stainless steel)	Different
Cytotoxicity	No cytotoxicity	Unknown	Different
Irritation	No intracutaneous reactivity		
Sensitization	No skin sensitization		
Acute Systemic Toxicity	No acute toxicity		
Material mediated pyrogenicity	No pyrogens		
Sterilization			
Method	EO Sterilized	EO Sterilized	Same

Different – Minimum working channel

The minimum working channel for proposed device is different from the predicate device K112994. The proposed 2.8mm working channel is same as the predicate device, while the proposed 2.0mm working channel is not covered by the predicate device. The reason for this difference is that the device balloon diameter for the proposed device and predicate device are not same. The different size will be selected by physician per patient's condition and this difference does not affect intended use. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different – Diameter of balloon

Compared with predicate devices, the balloon diameter of proposed device has a 4/5/6 specification, which is suitable for some very narrow parts and is more suitable for clinical needs. The difference does not raise different questions regarding its safety and effectiveness.

Different – Working Length

The working length for proposed device is different from the predicate device K112994. The proposed 1800mm specification is also included by the predicate device. While the proposed 900mm and 1200mm specifications are

shorter than the predicate device 1800 specifications,2000mm and 2300mm specification are shorter than the predicate device 2400 specifications. The different length will be selected by physician per patient's condition and this difference does not affect intended use. In addition, 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 – Performance

We conduct bench performance for our proposed device and the predicate device, please refer to Section 24 of this submission, the test results show that our proposed device is substantial equivalence with the predicate device.

Different-Biocompatibility

The patient contact material for the proposed device is different from the predicate device.The material of the Guide head and catheter that is proposed device to contact the human body is PA, and the material of the Guide head and catheter that is predicate device to contact the human body is Pebax,Actually PA and Pebax are both nylon. 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.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device, 3-Stage Balloon Dilation Catheter, is determined to be Substantially Equivalent (SE) to the predicate device K112994.