July 29, 2022

Jiangsu Vedkang Medical Science and Technology Co.,Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd.
P.O.box 120-119
Shanghai, 200120
CHINA

Re: K213914
Trade/Device Name: Injection Needle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: June 27, 2022
Received: June 29, 2022

Dear Diana Hong:

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,

Shanil P. Haugen, 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)*
K213914

Device Name
Injection Needle

Indications for Use *(Describe)*
The device is intended to be used with an endoscope to perform endoscopic vascular or submucosal injection in the GI 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.

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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: K213914

1. Date of Preparation: 01/24/2022

2. Sponsor Identification

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

Establishment Registration Number: 3013526170

Contact Person: Ting Tang
Position: Int'l RA
Tel: +86-519-69877791-8147
Email: tangting@vedkang.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd.
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Injection Needle
Common Name: Endoscopic Injection Needle

Regulatory Information
Classification Name: Endoscope and accessories
Classification: II;
Product Code: FBK
Regulation Number: 21 CFR 876.1500
Review Panel: Gastroenterology/Urology

Indication for use:
The device is intended to be used with an endoscope to perform endoscopic vascular or submucosal injection in the GI tract.

Device Description

The injection needle is intended to be used with an endoscope to perform endoscopic vascular or submucosal injection in the GI tract, which consists of needle, connector tube, guiding head, inner tube, outer tube, protective sleeve, front handle, injection handle, front handle cover and boosting tube. The proposed device is used to puncture the target tissue where guided by the endoscope. The fluid is injected to the target through the proposed device by an injector which is connected the proposed device.

5. Identification of Predicate Device

510(k) Number: K153625
Product Name: Single Use Injector NM600/610

6. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5:2009 Biological evaluation of medical Devices-Part 5: Tests for in Vitro Cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and skin sensitization.
- ISO 10993-11:2017 Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials. (Sterility)
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems(DL-13, Level II)
- ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications-Part 7: Connectors for intravascular or hypodermic applications
- ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals
- USP <85> Bacterial Endotoxins Test
- USP <151> Pyrogen Test

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics for Injection Needle

ITEM	Proposed Device	Predicate Device K153625	Remark
Product	Injection Needle	Single Use Injector NM600/610	/
Product Code	FBK	FBK	Same
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Class	Class II	Class II	Same
Indication for Use	The device is intended to be used with an endoscope to perform endoscopic vascular or submucosal injection in the GI tract.	This instrument has been designed to be used with an Olympus endoscope to perform endoscopic vascular or submucosal injection in the GI tract.	Same
Configuration	needle, connector tube, guiding head, inner tube, outer tube, protective sleeve, front handle, injection handle, front handle cover, boosting tube	Handle section, needle section, sheath section	Different
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			
Working Length	1200mm, 1800mm, 2300mm, 3000mm	1650mm, 2300mm	Different
Minimum working channel	2.0mm, 2.8mm	2.8mm	Different
Needle Size	19G, 20G, 21G, 22G, 23G, 25G	21G, 23G, 25G 26G	Different
Needle Length	3mm, 4mm, 5mm, 6mm, 8mm	3mm, 4mm, 5mm, 6mm, 1.8mm	Different
Patient contact material	Needle: S30400 Guiding Head: S30300 Inner Tube: PTFE or PP Outer Tube: PTFE or PP	Stainless steel PTFE	Different

	Injection Handle: ABS Boosting Tube: S30400		
Biocompatibility			
Cytotoxicity	No cytotoxicity	Comply with the ISO 10993 Standards	Same
Irritation	No intracutaneous reactivity		
Sensitization	No skin sensitization		
Systemic Toxicity	No systemic toxicity		
Pyrogen	No Pyrogen		
Hemolysis Properties	No Hemolysis		
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

Different - Configuration

The configuration for proposed device is different from the predicate device K153625. The proposed injection needle has the same main components as the predicate device, but the injection needle is configured in more detail than the predicate device. In addition, the performance tests were conducted on proposed device and predicate device, and the test result does not show any significant difference. Therefore, the difference in configuration will not affect the safety and effectiveness of the proposed device.

Different – Working Length

The working length for proposed device is different from the predicate device K153625. The proposed 2300mm specification is also included by the predicate device, and the proposed 1800mm specification can be covered in the working length range of predicate device. While the proposed 1200mm specification is shorter than the predicate device and 3000mm specification is longer than the predicate device. 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-Minimum Working Channel

The minimum working channel for proposed device is different from the predicate device K153625. 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 outer 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 – Needle Size

The needle size for proposed device is different from the predicate device K153625. For proposed needle size 20G to 25G, these specifications can be covered in the gauge ranges of predicate device. In addition to these specifications, the proposed device is available in 19G, which beyond the predicate device range. The different size 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 – Needle Length

The needle length for proposed device is different from the predicate device K153625. For proposed needle length 3mm to 6mm, these specifications are same as predicate device. In addition to these specifications, the proposed device is available in 8mm, which beyond the predicate device range. The different needle 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-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.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device, Injection Needle, is determined to be Substantially Equivalent (SE) to the predicate device K153625.