June 2, 2022

Beijing ZKSK Technology Co.,Ltd
℅ Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801,No.161,East Lujiazui Rd.,Pudong
Shanghai, Shanghai 200120
CHINA

Re: K213239
Trade/Device Name: Endoscopic Injection Needle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: II
Product Code: FBK
Dated: April 25, 2022
Received: April 29, 2022

Dear Boyle Wang:

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 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)*
K213239

Device Name
Endoscopic Injection Needle

Indications for Use *(Describe)*
Single use injection needle is to be used in conjunction with an endoscope to perform endoscopic injections, such as for the treatment of esophageal and gastric varies and for submucosal dye marking 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

K213239

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

Name: Beijing ZKSK Technology Co., Ltd
Address: Building 9, 6 & No.6 Yuan Hengye North 7th Street, Yongle Economic Development Zone, Tongzhou District,Beijing 101105, China
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Contact: Ma Li

Designated Submission Correspondent

Contact: Mr. Boyle Wang
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Tel: +86-21-50313932
Email: Info@truthful.com.cn

Date of Preparation: Apr.22, 2022

2.0 Device Information

Trade name: Endoscopic Injection Needle
Common name: Endoscopic Injection Needle, Gastroenterology-Urology
Classification name: Endoscope and accessories
Production code: FBK
Regulation number: 21 CFR 876.1500
Classification: Class II
Panel: Gastroenterology/Urology

3.0 Predicate Device Information

Manufacturer: Anrei Medical (Hangzhou) Co., Ltd.
Trade/Device Name: Single Use Injection Needle
510(k) number: K210917

4.0 Device Description

Endoscopic Injection Needle consists of Handle, Rod, Needle, Needle holder, Sheath, Catheter, Adapter, Sheath holder, Sheath protection pipe, Tube cap.

The Endoscopic Injection Needle is available in three needle sizes (20 gauges 22 gauge and 25 gauge), five needle lengths (4mm,5mm,6mm,8mm and 10mm),five working length(1200mm,1600mm, 1950mm,2000mm, 2300mm). There are 5 series (SN18-05 series, SN18-07 series, SN18-09 series, SN19-05 series and SN19-07 series) total ninety (90) specification injection needles.

The Endoscopic Injection Needle is sterile, single-use device. It is expected to be used in conjunction with an endoscope to perform endoscopic injections into tissue in the GI tract during an endoscopic procedure.

The Endoscopic Injection Needle is designed to pass through the endoscope's forceps to mark the lesions of the digestive tract and use it for injection.
Compatibility with endoscopes, working lengths are 1600mm, 1950mm,2000mm, 2300mm, and the minimum working clamp channel is φ 2.8 mm.

5.0 Indication for Use Statement

Single use injection needle is to be used in conjunction with an endoscope to perform endoscopic injections, such as for the treatment of esophageal and gastric varies and for submucosal dye marking in the GI tract.

6.0 Summary of Non-Clinical Testing

Summary of non-clinical and performance testing- Bench testing was performed to evaluate the performance and functionality of the subject device against requirement specification. The subject device has been subjected to compliance testing according to, by FDA, recognized consensus standards ISO 7864, ISO 9626,ISO 10993-7, ISO 10993-1, ISO 11607-1,and Technical Requirements of “Endoscopic Injection Needle” provided by Beijing ZKSK Technology Co., Ltd. Results from testing performed confirms that the design requirement specification and user needs have been met. The subject device is confirmed to be safe and effective for the intended use.

7.1 Sterilization and shelf life of Endoscopic Injection Needle is delivered sterile and have successfully been tested according to ISO 11607- 1. The label shelf life is 2 years.

7.2 Biocompatibility testing of Endoscopic Injection Needle has successfully been tested for hemolysis, cytotoxicity, sensitization, intracutaneously irritation, acute systemic toxicity and material medicated pyrogenicity. The test results verify that the biocompatibility criteria given in ISO 10993 are fulfilled. Endoscopic Injection Needle

is non-toxic and biocompatible.

7.3 Performance testing – Bench: The performance of Endoscopic Injection Needle has been verified. Tests as described in table 1 have been completed.

Table 1: Performance testing summary – Bench

Test Item	Description
Appearance	To confirm that subject device is integrity and cleanliness and hygiene.
Dimension	To confirm that the dimensions of the subject device complied with the company's requirements.
Leakage	There shall be no gas leakage.
Needle protection	Needle shall not be exposed when pulling rod back.
Resistance to corrosion	No corrosive marks should be found in the immersed part of the needle.
Stiffness	To confirm the needle tube is not easy to deform
Resistance to breakage	To confirm the needle tube is not broken during use
Penetrating force	Make sure the needle tip is sharp
Connection strength	To confirm all joints of the subject device is rigid connect.
Basic functional testing	To confirm the device can be successfully inserted and withdrawn into and out of an endoscope, and the stylet can pass through the syringe successfully.
Luer lock connectors	To confirm the performance of the luer lock connectors of the device meets the requirement of ISO 80369-7
Chemical properties	To confirm that pH, Total content of heavy metals, Potassium permanganate reductive substance, Evaporative residues and Ultraviolet Absorbance meet the related requirements.
Sterility	This device is sterilized by ethylene oxide. The device shall be sterile.
EO residue	EO residue shall be ≤10 μg/g.
Pyrogen	Shall be no pyrogen.

7.0 Summary of Clinical Testing

No clinical study is included in this submission.

8.0 Technological Characteristic Comparison Table

Table 2- Comparison of Technology Characteristics

Item	Subject Device	Predicate Device
510(k) No.	K213239	K210917
Product Name	Endoscopic Injection Needle	Single Use Injection Needle

Product Code	FBK	FBK
Regulation No.	21 CFR 876.1500	21 CFR 876.1500
Class	II	II
Indication for Use	Single use injection needle is to be used in conjunction with an endoscope to perform endoscopic injections, such as for the treatment of esophageal and gastric varies and for submucosal dye marking in the GI tract.	Single use injection needle is to be used in conjunction with an endoscope to perform endoscopic injections, such as for the treatment of esophageal and gastric varies and for submucosal dye marking in the GI tract.
Configuration	Endoscopic Injection Needle consists of Handle, Rod, Needle, Needle holder, Sheath, Catheter, Adapter, Sheath holder, Sheath protection pipe, Tube cap.	Needle, Connecting Tube, Inner Tube, Sheath, Protect Tube, Metal Tube, handle, Luer Connector
Minimal required working channel	2.8mm	2.8mm
Outer Sheath diameter	1.8mm,2.4mm	2.4mm
Needle size	20G, 22G, 25G	21G, 23G, 25G
Working Length	1200mm,1600mm, 1950mm,2000mm, 2300mm	1800mm, 2000mm, 2300mm
Needle Length	4mm, 5mm,6mm,8mm,10mm	4mm, 6mm
Patient Contact Material	Sheath: PTEF Catheter: SN18 series: Polypropylene(PP)/ SN19 series: Nylon (PA) Needle/ Needle holder: Stainless steel Rod: Acrylonitrile/butadiene/styrene copolymer (ABS)	Not publicly Available
Sterile	Ethylene Oxide, SAL: 10^{-6}	Ethylene Oxide, SAL: 10^{-6}
Shelf Life	2 years	3 years
Single Use	Single Use	Single Use
Biocompatibility	Conform with ISO10993-1 (ISO 10993-4,ISO10993-5, ISO10993-10, ISO10993-11)	Conform with ISO 10993 standards

The technological characteristics of the subject device are identical to those of predicate device. The subject device has the same basic design as the predicate device. The comparison between the subject and predicate devices is based on the

following:
• Same intended use
• Same indications for use
• Similar material types that meet ISO 10993 biocompatibility requirements
• Same sterilization methods
• Same fundamental technology/principal of operation/user interface

The outer sheath diameter of the subject device is different with that of the predicate device, but it does not affect the device compatibility with the endoscope of the minimum working cannel size of 2.8 mm.
The Needle size, working length and Needle Length of the subject device are larger than those of the predicate device, bench performance and Comparison testing including Stiffness testing, breakage testing, Penetration testing and Connection strength testing on the subject device and the predicate device shown the difference does not affect the device's safety and effectiveness, the subject device is substantially equivalent to the predicate device.

9.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicated device in K210917 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.