February 6, 2025

Beijing ZKSK Technology Co.,Ltd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, 200120
China

Re: K242192
Trade/Device Name: Disposable Sphincterotome
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: January 6, 2025
Received: January 7, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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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.

510(k) Number *(if known)*
K242192

Device Name
Disposable Sphincterotome

Indications for Use *(Describe)*
The Disposable Sphincterotome is indicated for use in transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. This device can also be used to cannulate and inject contrast medium.

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.

510(k) Summary

K242192

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.
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Contact: Mr. Boyle Wang
Name: Shanghai Truthful Information Technology Co., Ltd.
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Tel: +86-21-50313932
Email: Info@truthful.com.cn

Date of Preparation: Jan.14th, 2025

2.0 Device Information

Trade name: Disposable Sphincterotome
Common name: Sphincterotome
Regulation name: Endoscopic electrosurgical unit and accessories

3.0 Classification

Product code: KNS
Regulation number: 21 CFR 876.4300
Classification: Class II
Panel: Gastroenterology/Urology

4.0 Predicate Device Information

Manufacturer: Boston Scientific Corporation (BSC)
Trade/Device Name: Autotome™ RX
510(k) number: K013153

5.0 Device Description

The subject device Disposable Sphincterotome is a sterile, single-use endoscopic device, intended to be used with flexible endoscopes for intubation of the pancreaticobiliary system and for sphincterotome.
The disposable sphincterotome consists of cutting wire, sheath, guide wire connector, injection connector, conductive column, finger ring, handle, and imaging ring.
The subject device has 72 specifications. The differences among these models are the Cutting Length, Tip Length, Working Length and Type of guide wire lumen channel.
The subject device is EO sterilized to achieve the Sterility Assurance Level (SAL) of 10^{-6} and placed in a sterility maintenance package to ensure a shelf life of 3 years.
The main materials used for construction of Disposable Sphincterotome include PTFE, ABS, SUS304.

6.0 Indication for Use Statement

The Disposable Sphincterotome is indicated for use in transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. This device can also be used to cannulate and inject contrast medium.

7.0 Summary of Non-Clinical 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 10993-1, ISO 10993-7, ISO 11607-1, and Technical Requirements of "Disposable Sphincterotome" 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 Disposable Sphincterotome is delivered sterile and have successfully been tested according to ISO 11135 and ASTM 1980. The label shelf life is 3 years.
7.2 Biocompatibility testing of Disposable Sphincterotome has successfully been tested for 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. Disposable Sphincterotome is non-toxic and biocompatible.

7.3 Performance testing – Bench: The following bench tests were performed on Disposable Sphincterotome:

-- Appearance,
-- Dimension,
-- Operational Performance,
-- Tensile Performance,
-- Hydraulic Leak Resistance,
-- Injection Connector (Luer connectors) performance,
-- Conduction resistance,
-- Contrast Agent Injection Function
-- Cutting Line Function
-- Radiopacity
-- Compatible endoscopes tests
-- Thermal effect test

The results of all testing of Disposable Sphincterotome have been verified.

7.4 Electromagnetic Compatibility and Electrical Safety: Tests on Electromagnetic Compatibility and Electrical Safety were performed in accordance to requirements per IEC 60601-1:2020, IEC 60601-1-2:2020, IEC 60601-2-18:2009 and IEC 60601-2-2:2017.

8.0 Summary of Clinical Testing

No clinical study is included in this submission.

9.0 Technological Characteristic Comparison Table

Table 2- Comparison of Technology Characteristics

Item	Subject Device	Predicate Device	Remark
510(k) No.	K242192	K013153	/
Product Code	KNS	KNS	Same
Regulation No.	21 CFR 876.4300	21 CFR 876.4300	Same
Class	II	II	Same
Intended Use/Indication for Use	The Disposable Sphincterotome is indicated for use in transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. This device can also be used to cannulate and inject contrast medium.	The Autotome™ RX is indicated for use in transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. This device can also be used to cannulate and inject contrast medium.	Same
Injection	Contrast Medium	Contrast Medium	Same

Cutting Wire Length	10/20/25/30mm	20/30mm	Different
Compatible endoscopy working channel	≥2.8mm	≥2.8mm	Same
Compatible guidewire diameter	≤0.035 inch (Ø0.89mm)	≤0.035 inch (Ø0.89mm)	Same
Energy source	HF generator	HF generator	Same
Working Length	1800/2000/2300mm	2000mm	Different
Tip length	5/10/15mm	5mm	Different
Rated High-Frequency Voltage	1600 Vp (3200 Vp-p)	750Vp (1500Vp-p)	Different
Operation Output Power	30-40W	30-70W	Different
Sterile	Ethylene Oxide, SAL: 10^{-6}	Ethylene Oxide, SAL: 10^{-6}	Same
Single Use	Single Use	Single Use	Same
Biocompatibility	Conform with ISO 10993 -1	Conform with ISO 10993 -1	Same
Electromagnetic Compatibility and Electrical Safety	Conform with IEC 60601-1; IEC 60601-1-2; IEC 60601-2-2; IEC 60601-2-18	Conform with IEC 60601-1; IEC 60601-1-2; IEC 60601-2-2; IEC 60601-2-18	Same

The technological characteristics of the subject device are identical to those of predicate device. The subject device has the similar 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

1) The Cutting Wire Length, Working Length and Tip length range of the subject device are different from those of the predicate device. Performance testing was performed on the representative specifications that represent the worst-case design. The performance comparison testing was conducted with the predicate device and the candidate device to compare their physical performance. The test results showed that the differences don't affect the substantial equivalence. These differences will have no effect on the safety and effectiveness.

2) The Rated High-Frequency Voltage is different from the predicate device, and both devices had passed the safety and EMC testing.

3) Recommendations on Operation Output Power for the subject device is different from the predicate device. Performance comparison testing on Cutting Line Function under 30W, 40W, and 70W was performed and the test results showed that the subject device is as safe and effective as the predicate device.

Therefore, the differences between the proposed device and the predicated device are considered not to affect the Substantially Equivalency between the proposed and predicate devices concerning the safety and effectiveness.

10.0 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 K013153 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.