May 8, 2026

Zhejiang Soudon Medical Technology Co.,Ltd
℅ Nick Wang
RA Specialist
Shanghai Vanhe Consulting Co., Ltd
2F, Building No.1, 3938 Huqingping Road, Qingpu District
Shanghai, 210703
China

Re: K253013
Trade/Device Name: Disposable Stone Retrieval Balloon Catheter
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: GCA
Dated: September 6, 2025
Received: September 19, 2025

Dear Nick 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 C. Lee, Ph.D., M.B.A.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253013

Please provide the device trade name(s).

Disposable Stone Retrieval Balloon Catheter

Please provide your Indications for Use below.

This device is used for endoscopic removal of stones in the biliary system and for contrast injection.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

We submit this 510(k) Summary as per 21 CFR 807.92, it meets the content and format regulatory requirements.

5.1 Submitter

Submitted by:	Zhejiang Soudon Medical Technology Co.,Ltd Room 302-1,Floor 3, Building 4, No.1 Nangonghe Road, Donghu Street, Linping District, Hangzhou, Zhejiang, China
Establishment Registration Number	3025311469
Contact Person:	Nick Wang RA Specialist Shanghai Vanhe Consulting Co., Ltd Address: 2F, Building No.1, 3938 Huqingping Road, Qingpu District, Shanghai, China. Phone: 0086-13585860297 Email: vanheconsulting@126.com, yuriy@soudonmed.com
Date Prepared:	September 6, 2025

5.2 Device

Trade Name	Disposable Stone Retrieval Balloon Catheter
Device Name	Disposable Stone Retrieval Balloon Catheter
Common Name:	Disposable Stone Retrieval Balloon Catheter
Regulation Number:	21 CFR 876.5010
Regulation Description：	Biliary Catheter and Accessories
Regulatory Class:	Class II
Product Code:	GCA
Product Code Name	Biliary Catheter For Stone Removal That May Also Allow For Irrigation And Contrast Injection

5.3 Predicate Device

Trade Name:	/
Device Name	Stone Retrieval Balloon
Common Name:	Stone Retrieval Balloon
510(k) Number	K200173
Regulation Number:	21 CFR 876.5010
Regulation Name：	Biliary Catheter and Accessories
Regulatory Class:	Class II
Product Code:	GCA
Product Code Name:	Biliary Catheter For Stone Removal That May Also

	Allow For Irrigation And Contrast Injection

5.4 Device Description

The subject Disposable Stone Retrieval Balloon Catheter consists of catheter, balloon, marking tape, connector, connect catheter, injection port, wire guide port, balloon inflation port, with additional two-way valve and inflatable cylinder. All the catheter length is 2000 mm with an outer diameter of 2.5 mm. Due to the different guide wire exchange method, the models are divide into normal exchange models and rapid exchange methods, for rapid exchange models, there is a small hole on the catheter which is near the distal end, it is used to insert the guide wire rapidly. The balloon can be inflated to 9 mm, 12 mm, 15 mm, and 18 mm only for some models, and can be inflated to two sizes, 12-15 mm, or 15-18 mm for some models, and can be inflated to three size, 9-12-15 mm, or 12-15-18 mm for some models. Radiopaque bands placed at the distal and proximal ends of the balloon provide fluoroscopic visualization of the balloon location. The three lumens are balloon inflation port, wire guide port and injection port. The two-way valve is used at the proximal end of the balloon inflation port to control air movement into or out of the balloon. EO Sterilization and use for single use only.

5.5 Indication for Use:

This device is used for endoscopic removal of stones in the biliary system and for contrast injection.

5.6 Comparison of Technology Characteristics

Our proposed device Disposable Stone Retrieval Balloon Catheter is substantially equivalent to the predicate device. The differences between the Disposable Stone Retrieval Balloon 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**	**Comparison**
510k number		K253013	K200173	/
Technical	**Principles of operation**	Disposable Stone Retrieval Balloon Catheter achieves its target position through endoscopic working channel, utilizing the compliance of latex and the development ability of the development ring to achieve stone removal function.	Stone Retrieval Balloon achieves its target position through endoscopic working channel, utilizing the compliance of latex and the development ability of the development ring to achieve stone removal function.	Same.
	Structure	Disposable Stone	Stone Retrieval	Same.

Item		Proposed Device	Predicate device	Comparison
		Retrieval Balloon Catheter is comprised of a latex balloon mounted at the distal end of a Pebax catheter with three internal lumens.	Balloon is comprised of a latex balloon mounted at the distal end of a Pebax catheter with three internal lumens.	
	Balloon's Max OD	9mm, 12mm, 15mm, 18mm; 12-15mm, 15-18mm; 9-12-15mm, 12-15-18mm;	8.5/12/15/18/8.5-12-15/13-15-18mm	Same.
	Exchange method	Normal exchange, rapid exchange;	Normal exchange, rapid exchange;	Same.
	Catheter's max OD	2.5mm	2.4mm	Same.
	Working length	2000mm	2000mm	Same.
	Recommended Wire Guide Diameter inch	0.035inch	0.035 /0.025inch	Same
	Performance	- Sealing performance; - Corrosion Resistance; - Ray detectability; - Performance of luer taper; - Non hydration performance; - Wire passing performance; - Simulate channel passage performance; - Balloon burst performance; - Balloon filling tensile performance; - Connecting force; - Flow;	- Sealing performance; - Corrosion Resistance; - Ray detectability; - Performance of luer taper; - Non hydration performance; - Wire passing performance; - Simulate channel passage performance; - Balloon burst performance; - Balloon filling tensile performance; - Connecting force; - Flow;	Same.
Biological	**Materials or substances in contact with**	Pebax, Natural latex, Tal, Polyethylene Terephthalate,	Pebax, Tal, PET, Natural latex, UV-curing adhesive,	Different. Biocompatibility tests

Item		Proposed Device	Predicate device	Comparison
	human	Isobornyl acrylate, Poly(acrylic acid)	Polyurethane ink.	have been done for the difference. Biological risks are acceptable
	Biocompatibility	ISO 10993-5:2009 ISO 10993-10:2021 ISO 10993-23:2021 ISO 10993-11:2017	In Vitro Cytotoxicity Test: ISO 10993-5: 2009; Skin sensitization Test :ISO 10993-10: 2010; Intracutaneous Reactivity Test: ISO 10993-10: 2010;	
Single use		Yes	Yes	Same
Sterile supplied		Yes	Yes	Same

5.7 Applicable Guidance Document

NA

5.8 Performance Data

The Disposable Stone Retrieval Balloon Catheter meets all design specifications and medical device standards for biocompatibility (ISO 10993) and sterility (ISO 11135). The non-clinical performance meets the design specifications and shows substantial equivalence to the predicated device. The following summarizes the non-clinical bench testing conducted: Appearance, Balloon burst, balloon inflation, diameter of the sheath, working length, sealing performance, corrosion testing, performance of luer taper, non-hydration performance, wire passing performance, simulated channel passage, balloon filling tensile performance, connecting force, connection strength, flow testing, X-ray detection.

5.9 Clinical Test

No Clinical Study is included in this submission.

5.10 Conclusion

Based on the information provided in this premarket notification, Zhejiang Soudon Medical Technology Co., Ltd has demonstrated that proposed device Disposable Stone Retrieval Balloon Catheter is substantially equivalent to the predicate device.