



April 3, 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, 201703
China

Re: K253056
Trade/Device Name: Disposable Stone Extraction Basket
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: LQR
Dated: September 15, 2025
Received: September 22, 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 Lee, Ph.D., MBA
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.

K253056

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Please provide the device trade name(s).

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Disposable Stone Extraction Basket

Please provide your Indications for Use below.

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The device is used for the endoscopic removal of biliary stones and foreign bodies in the biliary system. The device is indicated for use in adult patient.

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)

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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 Address: 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 15, 2025

5.2 Device

Trade Name	Disposable Stone Extraction Basket
Device Name	Disposable Stone Extraction Basket
Common Name:	Disposable Stone Extraction Basket
Regulation Number:	876.5010
Regulation Description:	Biliary Catheter and Accessories
Regulatory Class:	Class II
Product Code:	LQR
Product Code Name	Dislodger, Stone, Biliary

5.3 Predicate Device

Trade Name:	Disposable Stone Extraction Basket
Device Name	Disposable Stone Extraction Basket
Common Name:	Disposable Stone Extraction Basket
510(k) Number	K201509
Regulation Number:	876.5010
Regulation Name:	Biliary Catheter and Accessories
Regulatory Class:	Class II
Product Code:	LQR

Product Code Name:	Dislodger, Stone, Biliary
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5.4 Device Description

The subject Disposable Stone Extraction Basket is comprised of a stainless steel/nitinol basket at the distal end of a sheath with handle. Basket is extended out of or retracted into the single lumen polytetrafluoroethylene catheter sheath using the handle component's actuator. The device is not compatible with any mechanical lithotripter. EO Sterilization and use for single use only.

5.5 Statement of Intended Use

The device is used for the endoscopic removal of biliary stones and foreign bodies in the biliary system. The device is indicated for use in adult patient.

5.6 Comparison of Technology Characteristics

Our proposed device Disposable Stone Extraction Basket is substantially equivalent to the predicate device. The differences between the Disposable Stone Extraction Basket and the predicate device do not raise any questions regarding its safety and effectiveness. The differences are listed in the table below.

Item	Proposed Device	Predicate device	Comparison	
Common name	Disposable Stone Extraction Basket	Disposable Stone Extraction Basket	/	
510k submitter	Zhejiang Soudon Medical Technology Co.,Ltd	Hangzhou AGS MedTech Co., Ltd.	/	
510k number	/	K201509	/	
Intended Use	The device is used for the endoscopic removal of biliary stones and foreign bodies in the biliary system. The device is indicated for use in adult patient.	The device is used for the endoscopic removal of biliary stones and foreign bodies.	Same	
Technical	Basket length	25mm/34mm/42mm/50mm	20mm/40mm/50mm	Different. The basket length of proposed device is in the range of the predicate device.
	Insert portion of maximum width	1.8mm, 2.4mm	2.0mm, 2.8mm, 3.7mm	Different. The difference among the proposed device

510(k) Summary
Disposable Stone Extraction Basket

Item		Proposed Device	Predicate device	Comparison
				and predicated device is acceptable by demonstrating in bench testing.
Biological	Materials or substances in contact with human	Nitinol, stainless steel, PTFE, ABS, PVC, Silica gel	Nitinol, stainless steel, PTFE	Different. Biocompatibility tests 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, Intracutaneous Reactivity Test ISO 10993.10-2010;	

The fundamental principle of operation for both the proposed device and predicate device are the same. There are differences in the proposed device and predicate device technology - Basket Length, Insert portion of maximum width and material. These differences between the Disposable Stone Extraction Basket and the predicate device were evaluated utilizing performance testing and do not raise any questions regarding its safety and effectiveness.

5.7 Applicable Guidance Document

NA

5.8 Performance Data

The Disposable Stone Extraction Basket meets all design specifications and medical device standards for biocompatibility (ISO 10993) and sterility (ISO 11135). Nonclinical bench testing demonstrate that the Disposable Stone Extraction Basket meets the performance criteria required to fulfill the intended use of the device.

The following summarizes the non-clinical bench testing conducted: □

- Appearance
- Size
- Connecting Performance
- Smoothness Performance
- Luhr Joint Performance
- Flexibility
- Stone Capture Performance

5.9 Clinical Test

No Clinical Study is included in this submission.



5.10 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, Based on the information provided in this premarket notification, Zhejiang Soudon Medical Technology Co.,Ltd has demonstrated that proposed device Disposable Stone Extraction Basket is substantially equivalent to the predicate device.