October 15, 2024

Scivita Medical Technology Co., Ltd.
Dan Jiang
Senior Regulatory Affairs Specialist
No. 2, Qingqiu Street, Suzhou Industrial Park
Suzhou, Jiangsu 215000
China

Re: K240192/A001
Trade/Device Name: Single-use Extraction Baskets
(EBF-1529S, EBF-1529C, EBF-1511C,
EBF-1511S, EBF-1506S, EBF-1506C,
EBF-1507S, EBF-1507C, EBF-1508S,
EBF-1508C, EBF-2029S, EBF-2029C,
EBF-2006S, EBF-2006C, EBF-2007S,
EBF-2007C, EBF-2008S, EBF-2008C)
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: Class II
Product Code: LQR
Dated: October 11, 2024
Received: October 11, 2024

Dear Dan Jiang:

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
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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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.

Submission Number *(if known)*

K240192

Device Name

Single-use Extraction Baskets (EBF-1529S, EBF-1529C, EBF-1511C, EBF-1511S, EBF-1506S, EBF-1506C, EBF-1507S, EBF-1507C, EBF-1508S, EBF-1508C, EBF-2029S, EBF-2029C, EBF-2006S, EBF-2006C, EBF-2007S, EBF-2007C, EBF-2008S, EBF-2008C)

Indications for Use *(Describe)*

The Single-use Extraction Baskets is intended for the endoscopic removal of stones and stone fragments in the biliary system.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Classification

Add a primary product code and any associated product codes below. You may type in the primary product code directly (only the product code field is required) or you may filter down by choosing first a medical specialty, regulation, then product code. If a device specific guidance is available for the product code, the guidance name and web link will be displayed. Use the Product Classification Website resource in the help text to obtain information about your product code and check the regulation text for any special controls that need to be considered (e.g, PAE and 21 CFR 890.3450). ?

Medical Specialty	Gastroenterology & Urology
Regulation	876.5010 - Biliary catheter and accessories
Product Code	LQR (Class 2) - Dislodger, Stone, Biliary

The primary product code of your device indicates a device specific guidance document is available to aid you in preparing a comprehensive submission. The document entitled "Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents; Final" is available at the link below. If you have any questions about applicability of this guidance, please contact the CDRH review Office.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/metal-expandable-biliary-stents-premarket-notification-510k-submissions

Associated Product Code(s) ?

510(k) #: K240192

510(k) Summary

Prepared on: 2024-10-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Scivita Medical Technology Co., Ltd.
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Correspondent Contact	Dan Jiang
Correspondent Contact Email	ra@scivitamedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Single-use Extraction Baskets (EBF-1529S, EBF-1529C, EBF-1511C, EBF-1511S, EBF-1506S, EBF-1506C, EBF-1507S, EBF-1507C, EBF-1508S, EBF-1508C, EBF-2029S, EBF-2029C, EBF-2006S, EBF-2006C, EBF-2007S, EBF-2007C, EBF-2008S, EBF-2008C)
Common Name	Biliary catheter and accessories
Classification Name	Dislodger, Stone, Biliary
Regulation Number	876.5010
Product Code(s)	LQR

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K203322	SpyGlass™ Discover Retrieval Basket	LQR

Device Description Summary

21 CFR 807.92(a)(4)

The Single-use Extraction Baskets is a single-use, sterile, disposable device. It is intended for the endoscopic removal of stones and stone fragments in the biliary system. The device consists of basket, sheath, and handle components. The basket component is constructed of stainless steel/nitinol wires. And the basket is connected to the handle of the operating portion through the insertion portion. Activating the handle allows the basket to open or close. This device is not compatible with any mechanical lithotripter.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Single-use Extraction Baskets is intended for the endoscopic removal of stones and stone fragments in the biliary system.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Single-use Extraction Baskets has the same intended use as the predicate device. Both the Single-use Extraction Baskets and predicate device are intended for the endoscopic removal of stones and stone fragments in the biliary system.

Technological Comparison 21 CFR 807.92(a)(6)

The subject Single-use Extraction Baskets and predicate device (K203322, SpyGlass™ Discover Retrieval Basket) share the similar technological characteristics. The differences in technological characteristics do not raise different questions of safety and/or effectiveness when compared to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following performance data were provided in support of the substantial equivalence determination. The test results demonstrated that the subject device complies with the standard requirements.
Biocompatibility testing
Biocompatibility testing is performed in accordance with the FDA Guidance, "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" including cytotoxicity, sensitization, and irritation testing.

Performance testing including sterilization validation, shelf life, and mechanical performance/bench testing was conducted to demonstrate the basic performance of the subject device and confirmed that the subject device performs as intended.

Sterilization validation
Sterilization validation was carried out with Methods Half-cycle approach in accordance with ISO 11135:2014.

Shelf life testing
Shelf life testing was conducted based on an accelerated aging test in accordance with ASTM F1980-21, the standard guide for accelerated aging of sterile barrier systems for medical devices. Three years real-time aging test will be performed to demonstrate longer stability and support the results of the accelerated aging test.

Mechanical performance testing
Mechanical performance testing was conducted on the following items to demonstrate the basic performance of the subject device and confirmed that the subject device performs as intended.
- Dimensions Testing
- Tensile Pull Testing
- Simulated-Use Functionality & Durability Testing
- Stone Capture Testing
- Deflection Testing

Comparative testing was conducted on the Single-use Extraction Baskets and the predicate SpyGlass Discover Retrieval Basket (K203322).

The clinical data is not applicable.

The nonclinical test were conducted to demonstrate that the subject is as safe and effective as the predicate.