March 26, 2025

Sb-Kawasumi Laboratories, Inc.
% Fumiaki Kanai
President
MIC International
4-32-16 Ryogoku
Sumida-ku, Tokyo 130-0026
Japan

Re: K241855
Trade/Device Name: SB Knife Jr2 (MD-47702 and MD-47702L)
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: February 20, 2025
Received: February 24, 2025

Dear Fumiaki Kanai:

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,

Shanil P. Haugen -S

Shanil P. 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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K241855

Device Name

SB Knife Jr2 (MD-47702 and MD-47702L)

Indications for Use *(Describe)*

The SB Knife Jr2 is a single-use sterile Electrosurgical Knife (Model Numbers: MD-47702, MD-47702L). This device is designed to be used with Olympus and ERBE Electrosurgical monopolar HF generators, connectors and patient grounding plates to cut tissue including Zenker's diverticulum within the digestive tract using high-frequency current.

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 – K241855

## 510(k) Summary

**a. Owner/Company name, address**

SB-KAWASUMI LABORATORIES, INC.
3-15-4 Tonomachi Kawasaki-ku, Kawasaki-shi, Kanagawa, 210-8602, Japan
Kenichi Inamura
Manager, Regulatory Affairs Department
Phone: +81-44-589-8070
Email: k-inamura@sb-kawasumi.jp

**b. Contact/Application Correspondent**

MIC International
4-32-16 Ryogoku, Sumida-ku, Tokyo, 130-0026, Japan
Fumiaki Kanai
President
Phone: 011-81-3-6659-5482
Email: kanaif@mici.co.jp

**c. Date prepared**

June 24, 2024

**d. Name of device**

| | |
|---|---|
| Trade/Proprietary Name: | SB Knife Jr2 (MD-47702 and MD-47702L) |
| Common/Usual Name: | Endoscopic Electrosurgical Knife |
| Regulation Description: | Endoscopic electrosurgical unit and accessories |
| Regulation Number: | 876.4300 |
| Classification Panel: | Gastroenterology – Urology Devices |
| Product Code: | KNS |
| Device Class: | II |

**e. Predicate devices**

| | |
|---|---|
| 510(k): | K190621 |
| Trade/Proprietary Name: | SB Knife® |
| Common/Usual Name: | Endoscopic Electrosurgical Knife |
| Regulation Description: | Endoscopic electrosurgical unit and accessories |
| Regulation Number: | 876.4300 |
| Classification Panel: | Gastroenterology – Urology Devices |
| Product Code: | KNS |
| Device Class: | II |

**f. Description of the device**

SB Knife Jr2 under application (Hereinafter "the Subject Device" is a single-patient use EtO-sterilized hand-held device that connects to an external high frequency (HF) generator and is designed to be used with Olympus and ERBE Electrosurgical monopolar HF generators, connectors and patient grounding plates to cut tissue including Zenker's diverticulum within the digestive tract using high-frequency current. Varying generator power, cycle and duration results in a control of these surgical capabilities. The Subject Device is designed to connect with Olympus and ERBE connectors and uses the disposable or reusable Olympus or ERBE grounding plates and connecting cables intended for the generators.

The Subject Device is not life supporting or life sustaining. It is designed as a short-term limited contact device (less than 24 hours), has no software, and has been certified to comply with IEC 60601-1, IEC 60601-2-2, IEC 60601-1-2, IEC 60601-1-6 and IEC 60601 2-18 by ISO 17025 accredited laboratory.

The Subject Device consists of two models as follows:
MD-47702 Working Length: 1970 mm
MD-47702L Working Length: 2320 mm

**g. Indications for Use**

**Indications for Use Statement**

The SB Knife Jr2 is a single-use sterile Electrosurgical Knife (Model Numbers: MD-47702, MD-47702L). This device is designed to be used with Olympus and ERBE Electrosurgical monopolar HF generators, connectors and patient grounding plates to cut tissue including Zenker's diverticulum within the digestive tract using high-frequency current.

**h. Technological Characteristics and Substantial Equivalence Discussion**

Subject Device is designed to perform Endoscopic Submucosal Dissection (hereinafter ESD) of digestive tract tissues and endoscopic dissection of Zenker's diverticulum and to work with the Olympus ESG-100 (K073207), ESG-400 (K103032) and the ERBE VIO-300D (K083452), ICC-200 (K080715) monopolar high-frequency electrosurgical generators, connectors and patient grounding plates.

The intended use of the Subject Device is identical to that of the Predicate device (SB Knife® K190621).

The comparison table for technological characteristics between the two devices is shown below.

Table 1 Comparison table for technological characteristics

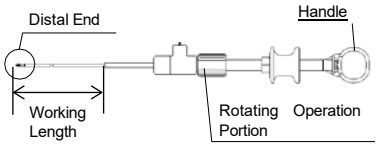
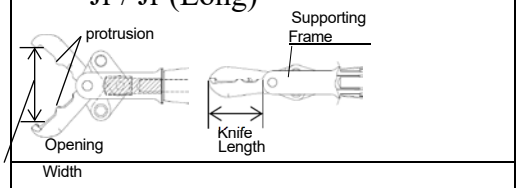
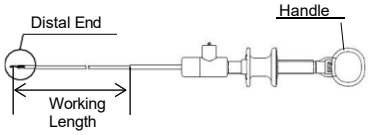
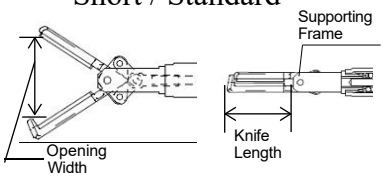
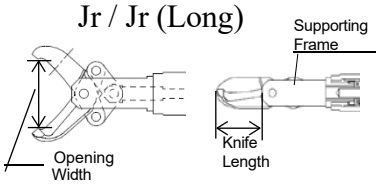
| Feature | Subject Device | SB Knife (Predicate device) (K190621) | Note |
|---|---|---|---|
| Indications for use | The SB Knife Jr2 is a single-use sterile Electrosurgical Knife (Model Numbers: MD-47702, MD-47702L). This device is designed to be used with Olympus and ERBE Electrosurgical monopolar HF generators, connectors and patient grounding plates to cut tissue including Zenker's diverticulum within the digestive tract using high-frequency current. | The SB Knife® is a single-use sterile Electrosurgical Knife (Model Numbers: MD-47703W, MD-47704, MD-47706 and MD-47703L). This device is designed to be used with Olympus and ERBE Electrosurgical monopolar HF generators, connectors and patient grounding plates to cut tissue including Zenker's diverticulum within the digestive tract using high-frequency current. | Identical |
| Type | Jr: MD-47702<br>Jr (Long): MD-47702L | Short: MD-47704<br>Standard: MD-47706<br>Jr: MD-47703W<br>Jr (Long): MD-47703L | Similar (*1) |
| Shape and Structure | Overall shape<br>  <br>Enlarged View of Distal End<br>Jr / Jr (Long)<br>  | Overall shape<br>  <br>Enlarged View of Distal End<br>Short / Standard<br>  <br>Jr / Jr (Long)<br>  | Similar (*1) |

Table 1 Comparison table for technological characteristics (continued)

| **Feature** | **Subject Device** | **SB Knife (Predicate device) (K190621)** | **Note** |
|---|---|---|---|
| Working Length | Model: Working Length:<br>MD-47702: 1970 mm<br>MD-47702L: 2320 mm | Model: Working Length:<br>MD-47704: 1800 mm<br>MD-47706: 1800 mm<br>MD-47703: 1950 mm<br>MD-47703L: 2300 mm | Similar |
| Opening Width | Model: Opening Width:<br>MD-47702: 4.5 mm<br>MD-47702L: 4.5 mm | Model: Opening Width:<br>MD-47704: 6 mm<br>MD-47706: 7 mm<br>MD-47703: 4.5mm<br>MD-47703L: 4.5 mm | Identical |
| Knife Length | Model: Knife Length<br>MD-47702: 3.5 mm<br>MD-47702L: 3.5 mm | Model: Knife Length<br>MD-47704: 6 mm<br>MD-47706: 7 mm<br>MD-47703: 3.5mm<br>MD-47703L: 3.5 mm | Identical |
| Rotating Operation Portion | Yes | No | Different (*2) |
| Materials | Forceps, Supporting Frame (Direct Body Contact)<br>Base Material: Stainless Steel<br>Coating Material: Polysiloxane<br>Handle, Slider: Polycarbonate<br>Rotating Operation Portion: Polycarbonate | Forceps, Supporting Frame (Direct Body Contact)<br>Base Material: Stainless Steel<br>Coating Material: Polytetrafluoroethylene<br>Handle, Slider: Polyphenylsulfone | Different (*3) (Materials other than left are identical) |

**Discussion regarding differences**

(*1) Type, Shape and Structure

The Subject Device has Jr / Jr (Long) type. SB Knife (Predicate device) has not only Jr and Jr (long) type, but also Short / Standard type.

Subject Device has protrusion to restrain from slipping of the grasped tissue.
Performance testing confirmed equivalent performance.

(*2) Rotating Operation Portion

Subject Device has Rotating Operation Portion, but SB Knife (Predicate device) does not have it. Forceps can be rotated in any direction by Rotating Operation Portion.

The Rotating Operation Portion is added for the purpose of improving handling. The function of the rotation prevention part was confirmed under Performance testing.

(*3) Materials

Coating material at Forceps, Supporting Frame of the Subject Device is Polysiloxane, whereas coating material at Forceps, Supporting Frame of Predicate Device is Polytetrafluoroethylene.
This part directly contacts body.
In clinical use, equivalent or better insulation and incision performance has been reported with changes in coating material. (See References)
The safety of changing materials has been confirmed by biocompatibility testing.

References

1. Yuzuru Tamaru *et al.* Endoscopic submucosal dissection of colorectal tumors using a novel monopolar scissor-type knife “SB Knife Jr.2”
   *Digestive Endoscopy 2019; 31: e105–e106*
2. Akihiro Maruyama *et al.*Water pressure method for endoscopic submucosal dissection using SB Knife Jr2 Digestive Endoscopy 2023; 35: e129–e130
3. Yasutoshi Shiratori *et al.*Introducing the newly developed SB Knife Jr 2: enhancing creative endoscopic submucosal dissection Article published online: 2020-11-19

Material of Handle, Slider, Rotating Operation Portion of SB Knife Jr2 (Proposed device) is Polycarbonate, whereas material of Handle, Slider of SB Knife (Proposed device) is Polyphenylsulfone. This part does not directly contact body.

**i. Non-Clinical Testing**

The following non-clinical testing was conducted to demonstrate the safety and efficacy of the subject device and confirmed that the subject device performs as intended.

- Transportation and Shelf life tests in accordance with ASTM D4169-22, ASTM D4332-14, ASTM F1980-21.
- Packaging test in accordance with ASTM F2096-11, ASTM F88/F88M-15.
- Sterilization validation in accordance with ISO 11135 Second edition 2014-07-15, ISO 10993-7 Second edition 2008-10-15.
- Electromagnetic compatibility test in accordance with IEC 60601-2-2 Edition 6.0 2017-03, IEC 60601-1-2 Edition 4.0 2014-02, and Electrical safety tests in accordance with IEC 60601-1 Edition 3.2 2020-08, IEC 60601-1-6 Edition 3.2 2020-07, IEC 60601-2-2 Edition 6.0 2017-03, IEC 60601-2-18: Edition 3.0 2009-08.
- Biocompatibility testing was conducted in accordance with ISO 10993-1 Fifth edition 2018-08

**j. Clinical Testing**

Clinical testing was not performed for the Subject Device.

**k. Conclusion**

Based on the above consideration, we concluded that the Subject Device is substantially equivalent to the SB Knife (Predicate device).