DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 17, 2016

Sumitomo Bakelite Co., Ltd.
% Michael Beeltje
Engineering Manager
Vaupell Corp.
101 HP Almgren Dr.
Agawam, MA 01001

Re: K152771
Trade/Device Name: SB Knife Jr Type, SB Knife Short Type, SB Knife Standard Type, SB Knife Jr Type - Long
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: May 2, 2016
Received: May 6, 2016

Dear Michael Beeltje,

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152771

Device Name
SB Knife Jr Type, SB Knife Short Type, SB Knife Standard Type, SB Knife Jr Type – Long

Indications for Use *(Describe)*
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 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.

005_ 510(k) Summary for SB Knife™

1. Submission Sponsor

Sumitomo Bakelite Co., Ltd.
Medical Products Business Division
5-8, Higashi-Shinagawa 2-chome, Shinagawa-ku,
Tokyo 140-0002, JAPAN

2. **Date Prepared**
May 2, 2016

3. Device Name

Trade/Proprietary Name:	SB Knife Jr Type, SB Knife Short Type, SB Knife Standard Type, SB Knife Jr Type - Long
Common/Usual Name:	Endoscopic Electrosurgical Knife
Classification Name:	Endoscopic electrosurgical unit and accessories
Classification Regulation:	876.4300
Classification Panel:	Gastroenterology – Urology Devices
Product Code:	KNS
Device Class:	II
FDA Establishment Registration #:	Not Available at time of Submission

4. Predicate Devices

Olympus Medical Systems, Corp. IT Knife/ IT Knife 2/ Hook Knife/ Flex Knife/ Triangle Tip Knife Electrosurgical Knife (K092309)

5. Device Description

The SB Knife™ 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 within the digestive tract using high-frequency current. Varying generator power, cycle and duration results in a control of these surgical capabilities. The SB Knives are designed to connect with Olympus and ERBE connectors and use the disposable or reusable Olympus or ERBE grounding plates and connecting cables intended for the generators.

The 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 and IEC 60601-2-2 and IEC 60601-2-18 by UL Japan

6. Indications for Use/Intended Use

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 within the digestive tract using high-frequency current.

7. Technological Characteristics and Substantial Equivalence

The SB Knife™ consists of four configurations:

7.1 SB Knife™ Standard (MD-47706), which has grasping forceps and standard length blade;
7.2 SB Knife™ Short (MD-47704), which has grasping forceps and shorter length blade;
7.3 SB Knife™ Jr (MD 47703W), which has crossing forceps and standard effective length;
7.4 SB Knife™ Jr – Long (MD 47703L), which has crossing forceps and longer effective length.

Choice of SB Knives' configurations is depend on Surgeon's/Physician's strategy for procedure, and length of endoscope used with, etc.

The SB Knife™ is substantially equivalent to the Olympus Systems, Inc. FlexKnife (K092309), having similar design, materials and configurations, intended use, indications for use. The SB Knife™ has demonstrated equivalency of use and results in side-by-side bench testing completed to defined test protocols on animal tissue, and been in use in Japan since 2009.

8. Non-Clinical Testing

The following testing has been performed to support substantial equivalence:

Comparative bench and animal tissue testing was performed for tissue ablation, resection, incision, cauterization, hemostasis, coagulation, vaporization and dissection of tissues using Olympus and ERBE monopolar HF generators. Testing resulted in equivalent performance to the predicate Olympus surgical knife.

Accelerated Aging and Actual Aging of Sterile Package Seal and product efficacy was completed and resulted in determination of a three-year product shelf life.

9. Clinical Testing

Clinical testing was not performed for this medical device.

10. Conclusion

The SB Knife™, as designed and manufactured, is substantially equivalent to the referenced predicate devices.