



May 8, 2018

Sumitomo Bakelite Co., Ltd
% Izumi Maruo
Senior Consultant
MIC International Corp.
4-1-17 Hongo
Bunkyo-ku, Tokyo 1130033
Japan

Re: K173004
Trade/Device Name: SB Soft Hood™
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDS
Dated: April 23, 2018
Received: April 26, 2018

Dear Izumi Maruo:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Charles Viviano -S

For 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

Indications for Use

510(k) Number (if known)

K173004

Device Name

SB Soft Hood™

Indications for Use (Describe)

SB Soft Hood is intended for use with SB Knife for endoscopic submucosal dissection within the gastrointestinal tract and for use in keeping the suitable depth of endoscopic field of view.

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.

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MEDICAL PRODUCTS BUSINESS DIV.

510 (k) Summary for SB Soft Hood™

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

April 23, 2018

3. Device Name

Trade/Proprietary Name: SB Soft Hood™
Common/Usual Name: Transparent Cap
Classification Name: Endoscope and accessories
Classification Regulation: 876.1500
Classification Panel: Gastroenterology – Urology Devices
Product Code: FDS
Device Class: II

4. Predicate Devices

Olympus Optical Corporation: Olympus Distal Attachment (K984358)

5. Device Description

SB Soft Hood™ is a transparent distal attachment applied to the tip of an endoscope. It is used in endoscopic submucosal dissection (hereinafter ESD) procedures. The subject device is used for maintaining visualization during the dissection phase of the procedure. The subject device is disposable and in a variety of diameters that correspond to different endoscope sizes. Each model of the subject device contains a drainage side hole that allows egress of water and blood.

6. Indications for Use

SB Soft Hood™ is intended for use with SB Knife for endoscopic submucosal dissection within the gastrointestinal tract and for use in keeping the suitable depth of endoscopic field of view.

7. Models of SB Soft Hood™

SB Soft Hood™ consists of six models as follows:

SB Soft Hood™ - Straight type (MD-47950)
SB Soft Hood™ - Undercut type (MD-47951)
SB Soft Hood™ - Straight type (MD-47960)
SB Soft Hood™ - Undercut type (MD-47961)
SB Soft Hood™ - Straight type (MD-47970)
SB Soft Hood™ - Undercut type (MD-47971)

Maximum outer diameters for MD-47950 and MD-47951, MD-47960 and MD-47961, and MD47970 and MD47971 are 13.0 mm, 14.8 mm, and 15.9 mm, respectively.

8. Technological Characteristics and Substantial Equivalence Discussion

SB Soft Hood™ is intended for use with SB Knife (K152771) for ESD within the gastrointestinal tract and for use in keeping the suitable depth of endoscopic field of view. The intended use of SB Soft Hood™ is similar to that of the Predicate Device (Olympus Distal Attachment K984358).

Both SB Soft Hood™ and the Predicate Device are attached to the tip of an endoscope in order to keep the distance between the tissue and the endoscope, and securing the endoscopic visual field.

However, the surgical device combined with SB Soft Hood™ is different from the device combined with the Predicate Device. SB Soft Hood™ is intended for use with SB Knife (K152771) which is used for ESD. The Predicate Device is intended for use with electric snare which is used for endoscopic mucosal resection (hereinafter EMR). (For detail about comparison for the use of the Subject and the Predicate Devices, please see following section 8.1.1)

Even though removed tissue area and depth are different between ESD and EMR procedures, both SB Soft Hood™ and the Predicate Device temporarily contact mucosal membrane and lesion of resected submucosal layer in the digestive system. Based on above, we determined that the indications for use of SB Soft Hood™ is substantially equivalent to that of the Predicate Device.

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

Table 1 Comparison table for technological characteristics


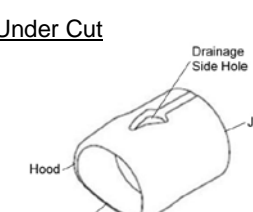
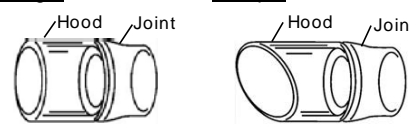
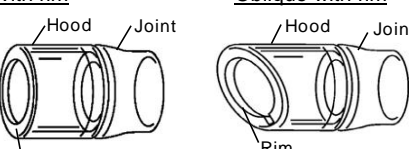
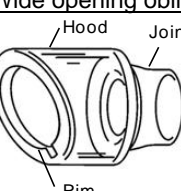
Feature	SB Soft Hood™	Predicate Device Olympus Distal Attachment (K984358)	Note
Indications for use			
Indications for use	SB Soft Hood™ is intended for use with SB Knife for endoscopic submucosal dissection within the gastrointestinal tract and for use in keeping the suitable depth of endoscopic field of view.	a) for use with electroscurgical snares for endoscopic mucosal resection within the gastrointestinal tract; and b) for use in keeping the suitable depth of endoscopic field of view	
Design and Materials			
Type	<u>Straight</u> : MD-47950, MD-47960, MD-47970 <u>Under Cut</u> : MD-47951, MD-47961, MD-47971	<u>Straight</u> : MH-462, MH-463, MH-464, MH-465, MH-466, MH-483, <u>Oblique</u> : MH-587, MH-588, MH-589, MH-590, MH-591, MH-592 <u>With rim</u> : MH-593, MH-594, MH-595, MH-596, MH-597, MH-598 <u>Oblique with rim</u> : MAJ-289, MAJ-290, MAJ-291, MAJ-292, MAJ-293, MAJ-294 <u>Wide opening oblique with rim</u> : MAJ-295, MAJ-296, MAJ-297	Similar (*1)
Shape and Structure	<p><u>Straight</u></p>  <p><u>Under Cut</u></p> 	<p><u>Straight</u> <u>Oblique</u></p>  <p><u>With rim</u> <u>Oblique with rim</u></p>  <p><u>Wide opening oblique with rim</u></p> 	Similar (*1)

Table 1 Comparison table for technological characteristics (Cont'd)

Feature	SB Soft Hood™	Predicate Device Olympus Distal Attachment (K984358)	Note
Maximum Outer Diameter	Model : Maximum Outer Diameter MD-47950 : 13.0 mm MD-47951 : 13.0 mm MD-47960 : 14.8 mm MD-47961 : 14.8 mm MD-47970 : 15.9 mm MD-47971 : 15.9 mm	Model : Maximum Outer Diameter MH-462, MH-587 : 12.6 mm MH-463, MH-588 : 13.5 mm MH-464, MH-589 : 14.8 mm MH-465, MH-590 : 16.6 mm MH-466, MH-591 : 17.2 mm MH-483, MH-592 : 19.0 mm MH-593 : 12.9 mm MH-594 : 13.9 mm MH-595 : 14.9 mm MH-596 : 16.6 mm MH-597 : 17.2 mm MH-598 : 19.2 mm MAJ-289 : 12.8 mm MAJ-290 : 13.8 mm MAJ-291 : 14.8 mm MAJ-292 : 16.6 mm MAJ-293 : 17.2 mm MAJ-294 : 19.1 mm MAJ-295, MAJ-296, MAJ-297: 16.1 mm	Similar (*2)
Suitable Outer Diameter of Endoscope	Model : Outer Diameter of Endoscope MD-47950, MD-47951 : 9.9 – 10.8 mm MD-47960, MD-47961 : 11.7 – 12.3 mm MD-47970, MD-47971 : 12.8 – 13.2 mm	Model : Outer Diameter of Endoscope MH-462, MH-587, MH-593 : 8.9 – 9.0 mm MAJ-289, MAJ-295 MH-463, MH-588, MH-594 : 9.2 – 10.3 mm MAJ-290, MAJ-296 MH-464, MH-589, MH-595 : 10.9 – 11.7 mm MAJ-291, MAJ-297 MAJ-663, MAJ-664 : 11.7 – 12.2 mm MAJ-666, MAJ-665 MH-466, MH-591, MH-597 :13.2 – 13.6 mm MH-293	Similar
Length of tip protrusion from Endoscope	Model : Length of tip Protrusion MD-47950, MD-47951 : 6 mm MD-47960, MD-47961 MD-47970, MD-47971	Model : Length of tip Protrusion MH-462, MH-463, MH-464 : 12 mm MH-465, MH-466, MH-483 MH-593, MH-594, MH-595 MH-597, MH-598 MH-587, MH-588, MH-589 : 13 mm MH-590, MH-591, MH-592 MAJ-289, MAJ-290, MAJ-291 : 14 mm MAJ-293, MAJ-294 MAJ-295, MAJ-296, MAJ-297	Different (*3)

Table 1 Comparison table for technological characteristics (Cont'd)

Feature	SB Soft Hood™	Predicate Device Olympus Distal Attachment (K984358)	Note
Drainage Side Hole	Yes	No	Different (*4)
Transparency	Yes	Yes	Similar
Number of Products Packaged	1 device per package.	1 device per package.	Identical
Sterilization Type	EO sterilized	Non sterilized	Different (*5)

Note (*1) – (*5): comparisons between SB Soft Hood and the Predicate Device are discussed in Section 8.1.2

8.1 Discussion regarding differences

8.1.1 Differences between ESD and EMR

The ESD procedure using SB Soft Hood™ and the EMR procedure using the Predicate Device

The use of SB Soft Hood™ is different from that of the Predicate Device because combined surgical device and surgical procedure using the combined device are different.

When SB Soft Hood™ attached to an endoscope is used in ESD procedure using SB Knife, SB Soft Hood™ is inserted under the incised mucosa and lifts it (**Figure 1**). SB Soft Hood™ maintains visualization during the dissection phase of the procedure, for supporting the submucosal dissection by SB Knife.

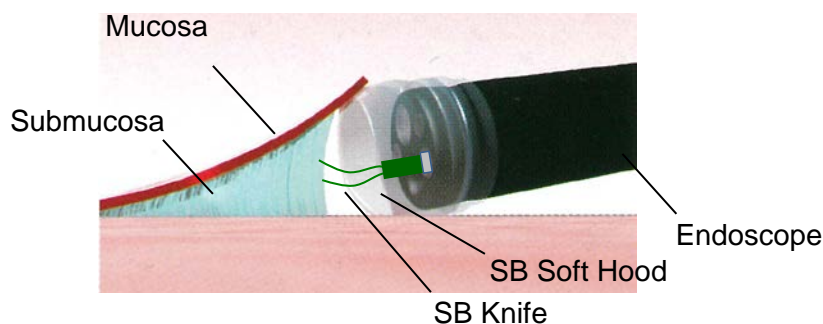


Figure 1 ESD procedure with the use of SB Soft Hood™

On the other hand, when the Predicate Device attached to an endoscope is used in EMR procedure using the electric snare, it is for use in keeping the suitable depth of endoscopic field of view, and for use as suction space of the lesion. **Figure 2** is EMR procedure with transparent cap extracted from the review article, “Endoscopic resection of early gastric cancer” provided by The International and Japanese Gastric Cancer Associations (IGCA & JGCA)¹.

The review article, “Endoscopic mucosal resection” provided by The American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee² explained about the EMR steps as follows;

“The endoscope is then immediately positioned over the target lesion, and suction is used to retract the mucosa into the cap after which the snare is closed to capture the lesion. The lesion is then resected with standard snare excision technique by using electrocautery.”



Figure 2 EMR procedure

8.1.2 Differences between SB Soft Hood™ and the Predicate Device for technological characteristics

(*1) Type, Shape and Structure

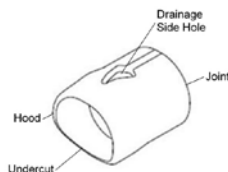
SB Soft Hood™ and the Predicate Device are similar in that they have “Joint” which is attached to the endoscope and “Hood” which keeps the endoscopic field of view. SB Soft Hood™ “Straight” type and the Predicate Device “Straight” type are similar in that they are straight at the tip of Hood. SB Soft Hood™ “Under Cut” type and the Predicate Device “Oblique” type are similar in that they are oblique at the tip of Hood.

SB Soft Hood

Straight

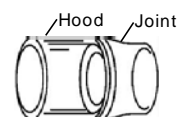


Under cut



Predicate Device

Straight



Oblique

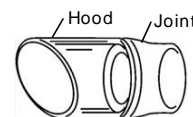


Figure 3 Schematics of SB Soft Hood™ and the Predicate Device

The rim of the Predicate Device is used for fixing the electrosurgical snare. Because SB Soft Hood™ is not used with the electric snare, it does not have types with the rim.

(*2) Maximum Outer Diameter

Maximum Outer Diameter is important for insertion into the esophagus, stomach or colon. Maximum Outer Diameter of SB Soft Hood™ is in range of 13.0 – 15.9 mm, and that of the Predicate Device is in range of 12.6 – 19.2 mm. Maximum Outer Diameter of SB Soft Hood™ is within the range of maximum Outer Diameter of the Predicate Device.

(*3) Length of tip protrusion from Endoscope

Length of tip protrusion from the tip of the endoscope for all the six models of SB Soft Hood™ is 6 mm. On the other hand, such length for the Predicate Device is in range of 12-14 mm. There is a difference, but both of devices can achieve their intended use respectively for following reasons;

As shown in **Figure 1**, SB Soft Hood™ lifts the mucosa. On the other hands, the Predicate Device is used as suction space (See **Figure 2**). The difference of length of tip protrusion between SB Soft Hood™ and the Predicate Devices is attributed to the different role for each surgical procedure.

(*4) Drainage Side Hole

SB Soft Hood™ has “Drainage Side Hole”, but the Predicate Device does not have it. Water and blood are easily to be accumulated in the Hood during ESD and interfere with the endoscopic field of view. “Drainage side hole” allows egress of water and blood for keeping clear vision. This function is necessary for securing the endoscopic field of view during ESD.

(*5) Sterilization Type

SB Soft Hood™ is EO sterilized, but the Predicate Device is not sterilized. Therefore, the risk of infection for SB Soft Hood™ is reduced than that for the Predicate Device. The Sterilization Validation was conducted in accordance with ISO 11135-1:2007. The Sterilization Validation demonstrated that the Sterility Assurance Level of 10^{-6} was achieved. Residual EO and ECH were not detected from the final product. In addition, endotoxin was not detected from the final product.

Furthermore, the material of SB Soft Hood is different from that of the Predicate device.

In order to evaluate any effects of the above differences on substantial equivalence, risk analysis, biocompatibility testing, sterilization validation, and shelf-life testing were conducted. The results of risk analysis and testing did not demonstrate any new concern compared to the Predicate Device. Based on the above consideration, we concluded that SB Soft Hood™ is substantially equivalent to the Predicate Device.

REFERENCES ESD procedure with the use of SB Soft Hood™

1. International and Japanese Gastric Cancer Associations; Takuji Gotoda, Endoscopic resection of early gastric cancer. *Gastric Cancer* 2007; 10:1-11
2. ASGE Technology Committee; Joo Ha Hwang, MD, PhD, FASGE, et al. Endoscopic mucosal resection. *GASTROINTESTINAL ENDOSCOPY* 2015;82:215-226

9. Design

For proper functioning of SB Soft Hood™, proper structure is a key. We identified following risks;

- inadequate length between distal end of the endoscope and the tissue
- poor view for endoscopic field
- disturbance of the endoscope
- interference by SB Soft Hood™ with the movement of SB Knife

Those risks were mitigated by proper designing of SB Soft Hood™.

10. Non-Clinical Testing

10.1 Biocompatibility testing

This testing was conducted because the material of SB Soft Hood™ is different from the Predicate Device.

SB Soft Hood™ directly contacts mucosal membrane and lesion of resected submucosal layer in digestive tract and categorized as Surface devices, Bleached or compromised surface, Contact duration A-limited ≤ 24 hours.

Accordingly, we performed following biocompatibility tests;

- Cytotoxicity
Standards: ISO 10993-5
Year: 2009
- Sensitization
Standards: ISO 10993-10
Year: 2010
- Acute systemic toxicity
Standards: ISO 10993-11
Year: 2006
- Irritation reactivity
Standards: ISO 10993-10
Year: 2010
- Material-mediated pyrogenicity
Standards: USPC 151
Year: 2005

In the biocompatibility testing reports, no biocompatibility concern was raised.

10.2 Performance testing

Visual inspection, durability testing, and detachment testing were performed to verify that the unaged and the aged SB Soft Hood™ remain attachment to an endoscope during actual clinical use. All samples met in-house standard which was determined based on expected worst-case.

10.3 Sterility testing

Sterility was evaluated by sterilization validation in accordance with ISO 11135-1:2007 and packaging integrity tests in accordance with ASTM F1929 and

ASTM F88/F88M. Residual EO and ECH testing were performed in accordance with ISO10993-7:2008 and endotoxin testing was performed in accordance with USP<85>. Residual EO and ECH and endotoxin were not detected.

11. Clinical Testing

Clinical testing was not performed for SB Soft Hood™.

12. Conclusion

Based on the above validation and verifications, we concluded that SB Soft Hood™ is substantially equivalent to the Predicate Device.