May 15, 2019

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

Re: K182520
Trade/Device Name: Flexible Overtube
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: FED
Dated: April 10, 2019
Received: April 12, 2019

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; 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 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,

for
Shani Haugen
Acting Assistant Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182520

Device Name
Flexible Overtube

Indications for Use *(Describe)*

Flexible Overtube is a device used in conjunction with a flexible endoscope for tissue or foreign body retrieval, and/or for endoscopic procedures requiring multiple endoscope intubations.

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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SUMITOMO BAKELITE CO., LTD.

5-8, HIGASHI-SHINAGAWA 2-CHOME, SHINAGAWA-KU, TOKYO 140-0002, JAPAN
PHONE: 81-3-5462-4811 FACSIMILE: 81-3-5462-4894

HEALTHCARE PRODUCTS DIV.

510 (k) Summary for Flexible Overtube™

1. Submission Sponsor

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

2. Date Prepared

September 5, 2018

3. Device Name

Trade/Proprietary Name:	Flexible Overtube™
Common/Usual Name:	Endoscopic access overtube
Classification Name:	Endoscope and accessories
Classification Regulation:	876.1500
Classification Panel:	Gastroenterology – Urology Devices
Product Code:	FED
Device Class:	II

4. Predicate Devices

US Endoscopy: Disposable Overtube (K040836)

5. Device Description

Flexible Overtube™ provides an access for repeated insertion and withdrawal of an endoscope for tissue or foreign body retrieval, and/or for endoscopic procedures requiring multiple endoscope intubations. Prior to inserting an endoscope into a patient, the user passes the endoscope through Flexible Overtube™. Flexible Overtube™ is placed after the endoscope is inserted into the patient. The endoscope can be inserted and withdrawn through properly placed Flexible Overtube™.

6. Indications for Use

Flexible Overtube™ is a device used in conjunction with a flexible endoscope for tissue or foreign body retrieval, and/or for endoscopic procedures requiring multiple endoscope intubations.

7. Technological Characteristics and Substantial Equivalence Discussion

Flexible Overtube™ is used in conjunction with a flexible endoscope for tissue or foreign body retrieval, and/or for endoscopic procedures requiring multiple endoscope intubations. The intended use of the subject device is identical to that of the Predicate device (Disposable Overtube K040836).

Prior to inserting an endoscope into a patient, the user passes the endoscope through Flexible Overtube™. Flexible Overtube™ is placed after the endoscope is inserted into the patient. The endoscope can be inserted and withdrawn through properly placed Flexible Overtube™.

The predicate device has the same principles of operation.

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

Table 1 Comparison table for technological characteristics

Feature:	**Flexible Overtube™**	**Predicate Device** **Disposable Overtube (K040836)**
Indications for use	Flexible Overtube™ is a device used in conjunction with a flexible endoscope for tissue or foreign body retrieval, and/or for endoscopic procedures requiring multiple endoscope intubations.	The disposable overtube is a device used in conjunction with a flexible endoscope for foreign body or tissue retrieval, and/or for endoscopic procedures requiring multiple endoscope intubations.
Overtube	Single tube system	Two-tube system
Design of distal end of the Overtube	The overtube has a soft and beveled distal end. The distal end has a lengthwise slit on short side.	Inner tube has a tapered distal end Outer tube has a soft and tapered distal end
Seal Unit	Detachable	Tethered to the outer tube
Mouthpiece	Detachable	Not provided.
Length	205 mm	250 mm model and 500 mm model
Inner diameter	16.0 mm	16.7 mm (Outer tube) 8.6 mm or 10.2 mm (Inner tube)
Outer diameter	19.0 mm	19.5 mm (Outer tube)

Endoscope OD range	9.0 mm to 12.0 mm	8.6 to 10.0 mm for 8.6 mm ID of inner tube 10.0 mm to 11.7 mm for 10.2 mm of inner tube
Sterility	Sterile	Non-sterile

There are some differences between the predicate and the subject devices as shown in the following:

A. Design of the Overtube:
Flexible Overtube™ uses single tube system. The Flexible Overtube™ has a soft and beveled distal end. The distal end has a lengthwise wide slit on short side. The shape of the distal end reduces the potential for mucosal pinching. On the other hand, the Disposable Overtube (K040836) uses a two-tube system. The tapered distal end of the inner tube fits with the endoscope and the system reduces the potential for mucosal pinching by withdrawing both the inner tube and the endoscope simultaneously from the patient. Therefore, both the proposed and the predicate devices provides an access for repeated insertion and withdrawal of an endoscope with reduced potential for mucosal pinching.

B. Seal Unit
The insufflation seal testing was conducted. The internal pressure of the proposed device's overtube with the seal unit was more than 4.0 kPa. The internal pressure is much more than the average of stomach pressure during insufflation.

C. Mouthpiece
It is recommended that a minimum 60FR bite block be used with the predicate device. Therefore, the use of the Flexible Overtube™ with the Mouthpiece is not different from the use of the predicate device.

D. Length
An overtube needs to be 20 to 25 cm in length if the overtube is intended to protect the cricopharyngeal area or the airway. (The American Society for Gastrointestinal Endoscopy (ASGE) Technology, 2009). The length of the Flexible Overtube™ is 205 mm and within the range. The predicate device includes models of 250 mm in length and 500 mm in length. The model of 250 mm in length is also within the range.

E. Sterility
The Flexible Overtube™ is EO sterilized, but the predicate device is not sterilized. Therefore, the risk of infection for the Flexible Overtube ™ is reduced than that for the predicate device. The Sterilization Validation was conducted in accordance with ISO 11135:2014. The Sterilization Validation demonstrated that the Sterility Assurance Level of 10^{-6} was achieved.

Residual EO and ECH of the final product did not exceed the allowable limit. In addition, endotoxin of the final product did not exceed the allowable limit.

F. Materials
The materials of the patient-contacting parts for the Flexible Overtube™ are different from those for the predicate device.

The Flexible Overtube™ directly contacts mucosal membrane in digestive tract and categorized as Surface devices, Mucosal membrane, Contact duration A-limited ≦24 hours .

Accordingly, we performed following biocompatibility tests;
- Cytotoxicity (ISO 10993-5: 2009)
- Sensitization (ISO 10993-10:2010)
- Acute systemic toxicity (10993-11:2006)
- Irritation reactivity (ISO 10993-10:2010)

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

In addition to evaluations above, tensile strength test and simulated use test were conducted. Those testing showed that the tensile strength of the proposed device is enough for the actual use and the bendability and stiffness of the Flexible Overtube™ were kept during endoscopic treatment.

8. Conclusion

Based on the considerations above, we concluded that the Flexible Overtube™ is substantially equivalent to the Disposable Overtube (K040836).

REFERENCE

ASGE Technology Committee; William M. Tierney, MD, Committee Chair, et al. Overtube use in gastrointestinal endoscopy. GASTROINTESTINAL ENDOSCOPY 2009; Vol 70: 828-834