March 19, 2020

Togo Medikit Co., Ltd.
℅ Izumi Maruo
Senior Consultant
MIC International
4-1-17 Hongo, Bunkyo-ku,
Tokyo, 113-0033, Japan

Re: K200379
Trade/Device Name: Super Sheath
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator For Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE, DYB
Dated: January 31, 2020
Received: February 18, 2020

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/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 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 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,

for

Misti Malone
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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)*
K200379

Device Name
Super Sheath

Indications for Use *(Describe)*
The device is indicated for use in the introduction of diagnostic and interventional devices inserted into the peripheral and coronary vasculature.

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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510(k) Summary

a. Owner/Company name, address

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c. Date prepared

March 19, 2020

d. Name of device

Trade Name:	Super Sheath
510(k) Type:	Special
Regulation Description:	Vessel dilator for percutaneous catheterization
Regulation Name:	Dilator, Vessel, For percutaneous catheterization
Regulation Number:	21 CFR 870.1310
Regulation Class:	II
Product Code:	DRE
Subsequent Product Code:	DYB
Classification Panel:	Cardiovascular

Hereinafter, the Proposed Device is called as “Super Sheath (Proposed)” in this submission because the predicate device has the same trade name.

e. Predicate device

Trade Name:	Super Sheath
510(k) Number:	K141070
Regulation Description:	Vessel dilator for percutaneous catheterization
Regulation Name:	Dilator, Vessel, For percutaneous catheterization
Regulation Number:	21 CFR 870.1310
Regulation Class:	II
Product Code:	DRE
Subsequent Product Code:	DYB
Review Panel:	Cardiovascular

Hereinafter referred as to "Super Sheath (K141070)" in this submission.

f. Description of the device

Major components of the Super Sheath (Proposed) are a sheath and a dilator. In addition, a guidewire is covered under this premarket notification. The guidewire is placed in the guidewire case including the inserter.

The sheath for the Super Sheath (Proposed) is named as the Super Sheath (Proposed) Introducer Sheath and is available in 4F- 9F diameters and in lengths ranging from 7 to 25 cm. Some types of sheaths have radiopaque markers. The Super Sheath (Proposed) are provided sterile and are intended for one procedure use only.

The one-piece construction of the sheath shaft and hub allows smooth passage of concomitantly used interventional medical devices. The sheath shaft and hub are made from Ethylene Tetrafluoro ethylene (ETFE) and polyamide.

The hubs contain a hemostatic valve to minimize blood leakage during a procedure. A side tube equipped with a three-way stopcock is attached to the sheath hub. The side tube extension may be used for fluid and medication administration, as well as blood sampling. Some types of sheaths contain a marker band that is embedded in the shaft approximately 2.0 mm from the distal tip.

The dilator is an open tapered plastic tube with an integral luer hub for guidewire insertion. The dilator is inserted into the introducer sheath. The dilator is longer than the sheath with a rounded tapered distal tip. The dilator facilitates and supports the entry of the sheath into the patient's vasculature. Once the sheath is in place, the dilator is removed. There are two different dilator distal tip sizes, 0.038" and 0.035" guidewire compatible. The 4F dilators are only available with a 0.035"guidewire lumen dilator. The 5-9F dilators are available with a 0.035" or 0.038" guidewire lumen. The 4-8F dilator tubes are made from Polypropylene (PP). The 9F dilator tubes are made from Fluorinated Ethylene Propylene. The dilator tubes are attached to the inner hub with a metal bush. The dilator is locked into the sheath by rotating motion.

The Super Sheath (Proposed) has a polypropylene suture wing which is color coded by French size. The suture wing is a small projection near the hub with a hole in it for correct

placement of the sheath using sutures.

The uncoated guidewire is made of a stainless steel coil wrapped tightly around an inner mandrel that tapers at the distal tip. The flexible tip is J-shaped available in diameters of 0.035" and 0.038". The guidewire, with inserter, is available in 45 cm and 80 cm lengths. The inserter is used strictly for guiding the guidewire into a cannula or introducer.

g. Indications for Use Statement

The device is indicated for use in the introduction of diagnostic and interventional devices inserted into the peripheral and coronary vasculature.

h. Comparative Information

The Super Sheath (Proposed) was modified from the Super Sheath (K141070). The Indications for Use statement for Super Sheath (Proposed) is identical to the predicate device. Technology/principal of operation and performance are also identical to the predicate device.

The Super Sheath (Proposed) contains the following modifications as compared to the predicate device:

- Change of material grade of the PP for the suture wing, the unvented cap, the dilator hub, the inner hub, and the vantage
- Change of mixing ratios of the additives including colorants for the suture wing and the dilator hub
- Change of material grade of the PP and addition of the new colorants for the dilator tube of 8F
- Non-colored upper cap from color coded by French size upper cap (The main resin is not changed)
- Dimension change of the luer lock connector of the inner hub
- Extension of shelf-life to three years from two years

Performance testing was done to support the modifications of the proposed device.

Following is a comprehensive comparison table between the proposed and predicate devices

Table 11-1. Comparison table for the Super Sheath (Proposed) and the Super Sheath (K141070)

Feature	Super Sheath (K141070)	Super Sheath (Proposed)
Indications for Use	The device is indicated for use in the introduction of diagnostic and interventional devices inserted into the peripheral and coronary vasculature.	Same
Prescription/OTC Use	Prescription	Same
Operation Principle	Manual	Same
Construction	Sheath, Dilator, Guidewire,	Same

	Guidewire case		
Single-use/Reusable	Single-use		Same
French Sizes Available	4F- 9F		Same
Effective Length	7 cm – 25 cm		Same
Radiopaque marker	Tantalum		Same
Sheath			
-Materials	Shaft: ETFE		Shaft: Same
	Sheath hub: Polyamide		Sheath hub: Same
	-Hemostatic valve: Isoprene rubber,		-Hemostatic valve: Same
	-Upper cap: Polyamide, colorants		-Upper cap: Polyamide
	-Suture wing: PP, polystyrene elastomer, colorants		- Suture wing: Material grade of the PP and mixing ratios of the additives including colorants are changed
	Sidearm holder: Polyamide		Sidearm holder: Same
	Side tube: Polyurethane		Side tube: Same
	Three-way stopcock: Polycarbonate, polyethylene		Three-way stopcock: Same
	-Unvented cap: Polystyrene elastomer, PP, colorants		- Unvented cap: Material grade of the PP is changed
-Sheath Shaft Inner Diameter (ID)	1.58 mm – 3.23 mm		Same
-Sheath Shaft Outer Diameter (OD)	1.98 mm – 3.69 mm		Same
Dilator			
-Dilator Tube Materials	4F −8F: PP, colorants, silicone oil 9F: Fluorinated ethylene propylene, colorants, silicone oil		4F, 5F, 6F, 7F, and 9F: Same 8F : Change of material grade of the PP and addition of a new colorant
-Dilator Tube Inner Diameter (ID)	4F-8F	0.92 mm – 1.00 mm (0.035” *)	Same
		1.02 mm– 1.10 mm (0.038” *)	
	9F	0.95 mm – 1.05 mm (0.035” *)	
		1.05 mm– 1.15 mm (0.038” *)	

- Dilator Tube Outer Diameter (OD)	1.38 mm – 3.09 mm	Same
- Dilator Tube Effective Length	13 cm – 31 cm (130 mm – 310 mm)	Same
- Dilator Distal Tip	0.035”* 0.038” *	Same
- Dilator Hub Materials	Dilator hub: PP, colorants	Material grade of the PP and mixing ratios of the additives including colorants are changed
	Inner hub: PP	Material grade of the PP is changed
Guidewire Tip Shape	J-tip	Same
Outer Diameter	0.035”, 0.038”	Same
Inserter	Available	Same
Sterilization method	Ethylene oxide	Same
Sterile Package	Pouch	Same
Shelf-Life	Two (2) years	Three (3) years

Note*: There are two different dilator distal tip sizes, 0.038" and 0.035" guidewire compatible. Note that the 4F dilators are only available with a 0.035"guidewire lumen dilator. The 5-9F dilators are available with a 0.035" or 0.038" guidewire lumen.

i. Performance data

Our risk analysis identified following verification/validation activities regarding the modifications to support substantial equivalence to the predicate device;

- Biocompatibility testing for material changed patient-contacting parts
- Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) testing
- Shelf-life testing for the sheath and the 8F dilator
- Performance testing for the 8F dilator

1. Biocompatibility testing

The nature of body contact and the contact duration of the Super Sheath (Proposed) are identical to those of the predicate device. Biocompatibility evaluation in agreement with recommendations in CDRH’s Biocompatibility Guidance entitled “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process’” was conducted. Based on our risk management procedures, biocompatibility testing for patient-contacting parts containing new PP, new colorant, and/or higher mixture ratio of some additives than the predicate device was conducted. We performed the following biocompatibility tests;

- Cytotoxicity
- Intracutaneous reactivity
- Sensitization
- Acute Systemic Toxicity
- Hemocompatibility

  - Hemolysis
  - Complement activation
  - Partial Thromboplastin Time
  - Platelet activation
  - in vivo Thromboresistance
- Material-Mediated Pyrogen test

2. Sterilization

No change has been made to the SAL, sterilization method, validation method and packaging from the submission under the Super Sheath (K141070).

Residual EO and ECH testing was conducted using an established method and exposure limit in conformity with ISO10993-7 and the submission under the predicate device without deviation. Residual EO and ECH in the Super Sheath (Proposed) did not exceed exposure limit.

3. Shelf-life

Three-year shelf-life testing for the dilator (except 8F), the guidewire and the packaging were conducted under a submission of the Super Sheath (K141070). Accordingly, the following shelf-life testing for the sheath and the 8F dilator was conducted using established methods and acceptance criteria in conformity with ISO 11070:2014 and the submission under the predicate device without deviation;

- Sheath shaft tensile testing
- Sheath kink testing
- Sheath hub to shaft tensile testing
- Valve integrity/sheath pressure testing
- Sheath lubricity testing
- Sheath radiopacity testing
- Cover tube durability testing
- Hemostatic valve integrity/sheath pressure testing
- Visual inspection on the dilator tube
- Dilator shaft tensile test
- Dilator hub to shaft tensile test

The sheath and the new 8F dilator maintain the physical performance for the three-year shelf-life.

4. Performance testing for the 8F dilator

The following performance testing for the 8F dilator was conducted;

- Visual inspection on the dilator tube
- Dilator shaft tensile test
- Dilator hub to shaft tensile test
- Dimensional analysis of the tip of the dilator tube

The visual inspection on the dilator tube, the dilator shaft tensile test, and the dilator hub to shaft tensile test were conducted using established methods and acceptance criteria in conformity with ISO 11070:2014 and the submission under the predicate device without deviation. The dimensional analysis demonstrated that dimension of the tip of the 8F dilator tube was in the range of the tolerance for the predicate device. The new 8F dilator of the Super Sheath (Proposed) met the acceptance criteria.

j. Conclusion

Test results demonstrated that all acceptance criteria were met; therefore, the device conforms to established product specifications and intended use. Based upon the same intended use and principle of operation, technology, and nonclinical testing it is concluded that the Super Sheath device (Proposed) is substantially equivalent to the predicate Super Sheath device (K141070).