September 17, 2024

Togo Medikit Co., Ltd.
Fumiaki Kanai
President
MIC International Corp.
4-32-16 Ryogoku
Sumida-ku
Tokyo, 130-0026
Japan

Re: K241230
Trade/Device Name: Super Sheath Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB, DRE
Dated: May 1, 2024
Received: May 2, 2024

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,

Sevan R. Oungoulian -S 2024.09.17 15:33:01 -04'00'

For
Misti Malone, PhD
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241230

Device Name
Super Sheath Introducer Sheath

Indications for Use *(Describe)*
The Super Sheath Introducer Sheath is indicated for use in the introduction of diagnostic and interventional devices inserted into the human vasculature of adult and pediatric patients of all ages.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

a. Owner/Company name, address

Togo Medikit Co., Ltd.
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Hyuga City, Miyazaki Prefecture, 883-0062, Japan
Daisuke Nagamizu, Manager, Regulatory Affairs Section, Quality Assurance Department
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b. Official Correspondent

Fumiaki Kanai, President
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Email: kanaif@mici.co.jp

c. Date prepared

September 10, 2024

d. Name of device

Trade Name: Super Sheath Introducer Sheath
Common Name: Introducer, Catheter
Classification Name: Catheter Introducer
Classification Regulation: 21 CFR 870.1340
Product Code: DYB
Classification Panel: Cardiovascular

e. Predicate device

510(k): K121504
Trade name: Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Set
Regulation Number: 21 CFR 870.1310
Product code: DYB

f. Description of the device

The Super Sheath Introducer Sheath (hereinafter referred to as the "Subject Device") is used to introduce diagnostic or interventional devices into a blood vessel. The Subject Device is available in two products: one consisting of a Sheath and Dilator (Super Sheath Introducer Sheath without Guidewire), and the other consisting of a Sheath, Dilator, and Guidewire (Super Sheath Introducer Sheath with Guidewire), similar to the Predicate Device K121504. These devices are provided sterile and intended for single use, and the shelf-life is three years.

The main component of the Sheath consists of a Sheath hub, a Sheath shaft connected to the Sheath hub, and a three-way stopcock valve connected to the hub with a side port tube. The Sheath shaft is 3.3 French size and available in 5cm and 7cm lengths. The Sheath hub contains a hemostatic valve and has a suture wing. The shape and dimensions of the three-way stopcock luer connector are modified to comply with the new applicable standard ISO 80369-7:2021.

The Dilator has an open, tapered plastic tube for Guidewire insertion. The Dilator tube is press-fit into the inner hub with a bushing. The length of the Dilator tube corresponds to the length of the Sheath shaft, which is longer and available in 10.5 cm and 12.5 cm.

The 0.018" Guidewire is the smallest size Guidewire and a 40 cm long, thin, flexible wire with a inserter attached to the tip. This Guidewire is a legally marketed product which is cleared by the Food and Drug Administration (K021990).

The upper cap and suture wing of the Sheath hub, and the Dilator hub are colored purple. The Dilator tube and the inserter are colored blue. And the unvented cap of the three-way stopcock is pink.

g. Indications for Use

The Super Sheath Introducer Sheath is indicated for use in the introduction of diagnostic and interventional devices inserted into the human vasculature of adult and pediatric patients of all ages.

h. Technological Characteristics

The following table compares the Super Sheath Introducer Sheath to the predicate device with respect to intended use and technological characteristics, providing more detailed information regarding the basis for the determination of substantial equivalence.

Feature	**Subject Device –Super Sheath Introducer Sheath – K241230**	**Predicate Device - Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets – K121504**	**Comparison**
French Sizes (available)	3.3F	3.3 F	**Same**
Indications for Use	Super Sheath Introducer Sheath is indicated for use in the introduction of diagnostic and	The Super Sheath Introducer Sheaths and Super Sheath Introducer	**Same**

	interventional devices inserted into the human vasculature of adult and pediatric patients of all ages.	Sheath Sets are indicated for use in the introduction of diagnostic and interventional devices inserted into the human vasculature of adult and pediatric patients of all ages.	
Regulation Number	870.1340	870.1340	**Same**
FDA Product Code	DYB	DYB	**Same**
Prescription/ OTC Use	Prescription	Prescription	**Same**
Components	Sheath, Dilator and Guidewire	Sheath, Dilator and Guidewire	**Same**
Single-Use/ Reusable	Single-Use	Single-Use	**Same**
Dimensional Comparison			
Effective Length	50 mm – 70 mm	50 mm – 70 mm	**Same**
Sheath Shaft Inner Diameter (ID)	3.3Fr	3.3Fr	**Same**
Three-way stopcock: luer lock connecter	Meets ISO 80369-7-21	Meets ISO 80369-7-21. This change has already been implemented and documented in the LTF.	**Same**
Dilator Tube Effective Length	105 mm + 5/-5 mm 125 mm + 5/-5 mm	105 mm + 5/-5 mm 125 mm + 5/-5 mm	**Same**
Dilator Distal Tip	0.018” (Only 0.018” size is available)	0.018” 0.021” 0.025"	**Different** Removal of the 0.021” and 0.025” sizes
Guidewire			
Tip Shape	Straight type	Straight type	**Same**
Outer Diameter	Max OD 0.018”	Max OD 0.018”	**Same**
Length - Nominal	400 mm ± 5 mm	400 mm ± 5 mm	**Same**
Sterilization and Shelf Life			
Sterilization Method	Ethylene Oxide	Ethylene Oxide	**Same**
Sterile Package	Pouch	Pouch	**Same**
Shelf-Life (Use By Date)	Three (3) years	Three (3) years	**Same**

i. Substantial Equivalence

Many of the materials of the Predicate Device are identical to that of the subject device excepting minor material changes for the Dilator tube, inserter and case tube components. In addition, there are changes in solvents in the manufacturing process. The changes were validated via performance

testing, sterilization validation, shelf-life testing, and biocompatibility testing including a biocompatibility risk assessment. The results of the validation testing and the risk assessment conducted demonstrated substantial equivalence when compared to the Predicate Device (K121504).

j. Bench Testing

The following bench tests were performed to demonstrate substantial equivalence to the Predicate Device (K121504) and verify conformity to the international standards and in-house requirements.

1. Sheath Shaft Tensile Test
2. Sheath Shaft Kink Test
3. Sheath Hub to Sheath Shaft Connection Strength Test
4. Sheath Hub to Side Tube Connection Strength Test
5. Three-Way Stop Cock to Side Tube Connection Strength Test
6. Sheath Hemostatic Valve Pressure Test
7. Sheath Pressure Test
8. Sheath Lubricity Test
9. Dilator Corrosion Resistance Test
10. Dilator Tube Tensile Test
11. Dilator Tube to Hub Connection Strength Test
12. Sheath Radiopacity Test
13. Guidewire Radiopacity Test

k.Biocompatibility Testing

We performed the following biocompatibility tests after risk assessment of biocompatibility.

1. Cytotoxicity
2. Intracutaneous reactivity
3. Sensitization
4. Acute Systemic Toxicity
5. Hemocompatibility
6. Pyrogen test
7. LAL test

l. Conclusion

Based on the above discussion and the enclosed sections regarding substantial equivalence to the predicate device, Togo Medikit Co., Ltd. concludes that the Subject Device is substantially equivalent to the Predicate Device (K121504), and the Subject Device does not raise any new questions regarding safety or effectiveness.