September 20, 2019

TOGO MEDIKIT Co., Ltd.
℅ Izumi Maruo
Senior Consultant
MIC International
4-1-17 Hongo
Bunkyo-ku, Tokyo 113-0033
JAPAN

Re: K190001
Trade/Device Name: Supercath 5
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: August 15, 2019
Received: August 19, 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/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 Nikhil Thakur
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
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)*
K190001

Device Name
Supercath 5

Indications for Use *(Describe)*
The Supercath 5 is intended to access a vein or artery and to administer fluids and/or blood. The Supercath 5 is designed for single use, and is designed to minimize inadvertent needlesticks and to reduce accidental needlesticks. The 18 - 22 gauge catheters may be used with power injectors at a maximum pressure of 300 psi.

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.

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510(k) Summary – K190001

a. Owner/Company name, address

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c. Date prepared

September 18, 2019

d. Name of device

Trade Name:	Supercath 5
Common Name:	Catheter, Intravascular, Therapeutic, Short-term less than 30 days
Regulation Name:	Intravascular Catheter
Regulation Number:	21 CFR 880.5200
Regulation Class:	II
Product Code:	FOZ
Classification Panel:	General Hospital

Hereinafter, the Proposed Device is called as "Supercath 5 (Proposed)" in this submission because predicate devices have the same trade name.

e. Predicate and reference devices

Predicate devices

The Supercath 5 (Proposed) has two predicate devices because those two devices altogether cover the sizes which the Supercath 5 (Proposed) includes.

Predicate Device for gauges 14G, 16G, 18G, 20G, 22G, and 24G

Trade Name:	Supercath 5
510(k) Number:	K140419
Common Name:	Catheter, Intravascular, Therapeutic, Short-term less than 30 days
Regulation Name:	Intravascular Catheter
Regulation Number:	21 CFR 880.5200
Regulation Class:	II
Product Code:	FOZ
Classification Panel:	General Hospital

Hereinafter "Supercath 5 (K140419)" in this submission. This predicate device is primary predicate.

Predicate Device for 26G

Trade Name:	Supercath 5
510(k) Number:	K172496
Common Name:	Catheter, Intravascular, Therapeutic, Short-term less than 30 days
Regulation Name:	Intravascular Catheter
Regulation Number:	21 CFR 880.5200
Regulation Class:	II
Product Code:	FOZ
Classification Panel:	General Hospital

Hereinafter "Supercath 5 (K172496)" in this submission.

Reference Devices

Trade Name:	Supercath 6
510(k) Number:	K160592
Common Name:	Catheter, Intravascular, Therapeutic, Short-term less than 30 days
Regulation Name:	Intravascular Catheter
Regulation Number:	21 CFR 880.5200
Regulation Class:	II
Product Code:	FOZ
Classification Panel:	General Hospital

f. Description of the device

The Supercath 5 (Proposed) is intended to access a vein or artery and to administer fluids and/or blood. The Supercath 5 (Proposed) is designed for single use, and is designed to minimize inadvertent needlesticks and to reduce accidental needlesticks. The 18 - 22 gauge catheters may be used with power injectors at a maximum pressure of 300 psi.
The maximum flow rate and maximum pressure setting for each catheter size are listed in the table shown as follows. The maximum flow rate may vary due to differences in injector characteristics, injectate viscosity and temperature, and other variables.

Table 1. The maximum flow rate and the maximum pressure setting

Gauge	Length		Maximum Flow Rate (mL/sec)	Maximum Pressure (psi)
	(in)	(mm)		
22G	1	25	7	300
22G	1 1/4	31	7	300
20G	1	25	9	300
20G	1 1/4	31	9	300
20G	2	50	9	300
18G	1 1/4	31	12	300
18G	2	50	12	300

The Supercath 5 (Proposed) catheter hub has a built-in check valve which together with the healthcare professional's finger pressure on the blood vessel, assists to reduce blood flashback when the metallic introducer needle is withdrawn following blood vessel puncture. The built-in check valve is not intended to stop bleeding completely. Pressing the button on the needle hub activates the coiled spring in the hub, retracting the metallic introducer needle into the needle hub.

The Supercath 5 (Proposed) introducer needle has a side-notch to provide rapid visual confirmation of vessel entry. When the introducer needle is inserted into the vein, blood flows up and through the side-notch and returns down along the inside of the catheter tube.

The Supercath 5 (Proposed) is available in 14G, 16G, 18G, 20G, 22G, 24G and 26G.

g. Indications for Use Statement

The Supercath 5 is intended to access a vein or artery and to administer fluids and/or blood. The Supercath 5 is designed for single use and is designed to minimize inadvertent needlesticks and to reduce accidental needlesticks. The 18 - 22-gauge catheters may be used with power injectors at a maximum pressure of 300 psi.

h. Comparative Information

The Supercath 5 (Proposed) was modified from the Supercath 5 (K140419) and the Supercath 5 (K172496). The primary difference in the Supercath 5 (proposed) is the indications for use statement includes administration of blood and 18-22 gauge catheters may be used with power injectors. These changes do not affect the intended use of the device compared to the predicates.

Technological characteristics

The similarities of the subject device to the predicate devices are:

- Same catheter material (Polyurethane)
- Radiopaque
- Flashback Visualization
- Side-Notch Needle
- Same Needlestick Injury Prevention Feature
- Check Valve
- Ethylene Oxide Sterilized
- Single Sterile Wrapped
- Multiple Gauge Sizes and Needle Lengths

The Supercath 5 (Proposed) contains following modifications as compared to the predicate devices:

- Change of material formulation of the plug, the wing, the plunger, the cap, and the protector
- The adjustable attachment on the tip of the grip is not used for all models
- Addition of a packing part for blood on the needle hub for all models
- Addition of power injection to 18G, 20G, and 22G
- Addition of administration of blood in the Indications for Use

Performance testing was done to support the modifications of the subject device

Followings are comprehensive comparison table for the proposed, predicate, and reference devices:

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Table 2 Comparison table between the Supercath 5 (Proposed), the predicate and the reference devises

Item	Supercath 5 (Proposed)	Predicate Devices		Reference Device	Substantial Equivalence Analysis
		Supercath 5 (K140419)	Supercath 5 (K172496)	Supercath 6 (K160592)	
Indications for Use Statement	The Supercath 5 is intended to access a vein or artery and to administer fluids and/or blood. The Supercath 5 is designed for single use, and is designed to minimize inadvertent needlesticks and to reduce accidental needlesticks. The 18 - 22 gauge catheters may be used with power injectors at a maximum pressure of 300 psi.	The Supercath 5 is intended to access a vein or artery and to administer fluids. The Supercath 5 is designed for single use and for short-term use (less than 30 days), is designed to minimize inadvertent needlesticks and to reduce accidental needlesticks.	The Supercath 5 is intended to access a vein or artery and to administer fluids. The Supercath 5 is designed for single use, and is designed to minimize inadvertent needlesticks and to reduce accidental needlesticks.	The Supercath 6 is intended to access a vein or artery and to administer fluids. The Supercath 6 is designed for single use and for short-term use (less than 30 days), is designed to minimize inadvertent needlesticks and to reduce accidental needlesticks. The 18 - 22 gauge catheters may be used with power injectors at a maximum pressure of 300 psi.	Substantially equivalent. For detail about substantial equivalence analysis for Indications for Use statement, please see above.
Needlestick injury prevention feature	The metallic introducer needle is retracted into the needle hub when the activation button on the needle hub is pressed.				Same
Flashback visualization	Yes	Yes	Yes		Same.
Side-notch needle*[1]	Yes	Yes	Yes		Same

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Item	Supercath 5 (Proposed)	Predicate Devices		Reference Device	Substantial Equivalence Analysis
		Supercath 5 (K140419)	Supercath 5 (K172496)	Supercath 6 (K160592)	
Radiopaque	Yes	Yes	Yes		Same
Adjustable attachment*2	No	Yes	No		Please see *2
Additional packing part for blood on the needle hub*3	Yes	No	No		Performance data
Sterilization	Ethylene oxide	Ethylene oxide	Ethylene oxide		Same
Packaging	Blister	Blister	Blister		Same.
Use with Power Injectors (18G, 20G, 22G)	Yes	No	No	Yes	Performance Data
Multiple gauge sizes and needle length	Yes (14G, 16G, 18G, 20G, 22G, 24G, and 26G)	Yes (14G, 16G, 18G, 20G, 22G, and 24G)	26G		The two predicate devices altogether cover the sizes which the Supercath 5 (Proposed) includes.
Material of catheter tube	Polyurethane	Polyurethane	Polyurethane		Same

*1: Side-notch needle is the introducer needle with a side-notch, to provide rapid visual confirmation of vessel entry. When the introducer needle is inserted into the vein, blood flows upward into the side-notch and returns down along the inside of the catheter tube. This does not affect the intended use of the device.
*2: The adjustable attachment is used just when manufacturing the Supercath 5 (K140419). The attachment is used in order to adjust the distance between the tip of the introducer needle and the tip of the catheter. This does not affect the intended use of the device.
*3: The packing part on the needle hub improves the prevention of the escape of blood outside the device. This does not affect the intended use of the device.

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i. Performance data

Evaluations of the modifications in support of the substantial equivalence determination is shown below;

1. Biocompatibility testing

The Supercath 5 (Proposed) contacts patient's skin and blood and is categorized as an External communicating, Circulating blood contact device with a Prolonged contact duration in accordance with ISO 10993-1:2009 and referencing FDA guidance entitled "Use of International Standard ISO 10993- 1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The nature of contact with the body and the category of the Supercath 5 (Proposed) are identical to those of the predicate devices.

Biocompatibility testing was leveraged from the sponsor's own predicate devices (K140419 and K172496).

The addition of administration of blood in the Indications for Use is supported by the Hemocompatibility testing (hemolysis, complement system, coagulation, platelets, and thrombosis) performed on the sponsor's own reference device (K160592).

2. Power injection test

Catheter burst pressure exceeds the peak pressure present in the catheter at maximum flow conditions when tested according to ISO 10555-1:2013.

3. Vent fitting test for the needle hub

The needle hub with the packing part is impervious to liquid infiltration when subjected to positive pressure in accordance with ISO 10555-5:2013.

4. Flow rate test

The flow rate through catheter meets allowable limits when tested according to ISO 10555-1:2013.

5. Ease of assembly performance testing for the plunger

The plunger passes through the check valve when tested according to ISO 594-2:1998 section 5.6.

6. Tensile strength testing for the cap

The tensile strength of the cap meets acceptable minimum force until breakage when tested according to in-house standard.

7. Sterilization validation in accordance with ISO 11135:2014 and shelf-life testing were conducted.

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The results of testing above did not raise any new questions of safety or effectiveness.

j. Conclusion

Based on the Indications for Use, technological characteristics, and performance testing, Togo Medikit concludes that the Supercath 5 (proposed) is substantially equivalent to the predicate devices.