March 23, 2018

TOGO Medikit Co., Ltd.
Daisuke Nagamizu
Manager, Regulatory Affairs Section, Quality Assurance Department
17148-6 Aza Kamekawa
Oaza Hichiya
Hyuga City, Miyazaki 883-0062
JAPAN

Re: K172496
Trade/Device Name: Supercath 5 (26g)
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: February 8, 2018
Received: February 12, 2018

Dear Daisuke Nagamizu:

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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K172496

Device Name
Supercath 5 (26G)

Indications for Use *(Describe)*
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.

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: K172496

a. Owner/Company name, address

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c. Device information

Device Name:	Supercath 5 (26G)
Regulation Number:	21 CFR 880.5200
Classification Name:	Catheter, Intravascular, Therapeutic, Short-term less than 30 days
Product Code:	FOZ - Intravascular Catheter

d. Predicate device

Device Name:	Supercath 5
510(k) Number:	K140419
Product Code:	FOZ - Intravascular Catheter

e. Date prepared

August 14, 2017

f. Indications for Use

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.

g. Description of the device

The Supercath 5 (26G) is intended to access a vein or artery and to administer fluids. The Supercath 5 (26G) is designed for single use, and is designed to minimize inadvertent needlesticks and to reduce accidental needlesticks.
This device is a single-use and provided with ethylene oxide (EO) sterilization. Its shelf life is 3 years. The device is available in 26G and effective length of 19mm.

The introducer needle of the Supercath 5 (26G) has a side-notch to provide rapid visual confirmation of vessel entry. When the introducer needle is inserted into a vessel, blood passes through the side-notch and flows back along the inside of the catheter.

The Supercath 5 (26G) has a safety system. Pressing an activation button results in retracting the metallic introducer needle into a safety cover. This safety system enables to avoid needle-stick accident and further exposure of blood or body fluid attached to the introducer needle.

Some versions of the Supercath 5 (26G) have a built-in check valve which together with a healthcare professional's finger pressure on a blood vessel assists to reduce blood flashback during and after the retraction of the metallic introducer needle to the safety cover until the connection of an infusion or transfusion set to the catheter hub. The built-in check valve is not intended to stop bleeding completely.

h. Comparison to the Predicate device

The Supercath 5 (26G) is the line extension of the predicate device Supercath 5 cleared under K140419 (14 - 24G). As shown in the table below, the subject device (26G) has the same indications for use and the same design, material, and technological characteristics as the predicate device.

The primary difference between these devices is the gauge size. However, it is considered that this difference does not effect on the indications for use of the Supercath 5 (26G) because their general design, material, and technological characteristics are the same.

Comparison table with the predicate device

Parameter	Subject device	Predicate device
	Supercath 5 (26G)	Supercath 5
Whole device		
Manufacturer	Togo Medikit Co., Ltd	Togo Medikit Co., Ltd
510(k) Number	TBD	K140419
Indications for Use	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 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.
Single use/Reusable	Single use	Single use
Sterilization method	Ethylene Oxide	Ethylene Oxide
Shelf life	3 years	3 years
Dimensions		
Gauge size	26G	14-24G
Physical Characteristics		
Check valve	Optional	Optional
Wing	Optional	Optional
Side-notch	Included	Optional
Safety system	Included	Included
Materials		
Outer needle	Polyurethane, Polycarbonate etc.	Polyurethane, Polycarbonate etc.
Inner needle	Stainless steel, Polycarbonate etc.	Stainless steel, Polycarbonate etc.
Packaging		
Unit Package	Blister package	Blister package

i. Sterilization and pyrogenicity

The Supercath 5 (26G) is EO sterilized and is intended for single-use. Following shows the information on the sterilization and its validation method of the device.

Sterility Assurance Level (SAL):	10^{-6}
Sterilization method:	20% Ethylene Oxide sterilization
Method used to validate the sterilization cycle:	ISO 11135-1 (half cycle)

The Supercath 5 (26G) is labeled as nonpyrogenic. End-product Endotoxin testing per "USP 30 Chapter <85> Limulus Amebocyte Lysate (LAL) Testing" is performed prior to release of each batch.

j. Biocompatibility

The following test data on biocompatibility was assessed to verify conformity to the ISO10993-1 and "FDA guidance on Use of International Standard ISO 10993-1" to demonstrate substantial equivalence to the predicate device.

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity
- Systemic toxicity (acute)
- Material Mediated Pyrogenicity
- Systemic toxicity (subacute)
- Systemic toxicity (subchronic)
- Genotoxicity
- Implantation
- Haemocompatibility

k. Performance testing - Bench

The following performance data was assessed to verify conformity to standards (ISO10555-1, ISO594-1, ISO594-2, ISO10555-5, ISO11607-1 and ASTM F1980), and to demonstrate substantial equivalence to the predicate device.

- Overview
- Tensile Strength
- Leakage
- Flow rate
- Simulated clinical use
- Package integrity

l. Conclusion

Based on the discussion above, Togo Medikit concluded that the Supercath 5 (26G) was substantially equivalent to the predicate device.