DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 12, 2016

TOGO MEDIKIT CO., LTD.
c/o Izuni Maruo
MIC International
4-1-17 Hongo
Bunkyo-ku, Tokyo 113-0033
JAPAN

Re: K160592
Trade/Device Name: SUPERCATH 6
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: II
Product Code: FOZ
Dated: July 13, 2016
Received: July 14, 2016

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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160592

Device Name
SUPERCATH 6

Indications for Use *(Describe)*
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

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-K160592

a. Owner/Company name, address

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c. Date prepared

February 29, 2016

d. Name of device

Trade Name:	SUPERCATH 6
Common Name:	Intravascular Catheter
Classification Name:	Catheter, Intravascular, Therapeutic, Short-term less than 30 days
Classification Regulation:	21 CFR 880.5200
Product Code:	FOZ
Classification Panel:	General Hospital

e. Predicate/reference devices

The SUPERCATH 6 is substantially equivalent to the following legally marketed devices:

Predicate device

510(k):	K140419
Trade name:	SUPERCATH 5
Product code:	FOZ

This submission uses a reference device for the power injection and changes in indications for use statement from the predicate device:

Reference device

510(k):	K111236
Trade name:	Introcan Safety® 3 Closed IV Catheter
Product code:	FOZ

f. Description of the device

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) 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 6 has technological characteristics as follows;

Its 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 introducer needle of the SUPERCATH 6 has a side-notch to provide rapid visual confirmation of vessel entry. When the introducer needle is inserted into the vein, blood flows upward into side-notch and returns down along the inside of the catheter tube.

The SUPERCATH 6 has a slide in order to assist insertion of the catheter. The user can choose either to push the catheter hub forward or push the slide forward to insert the catheter. When pushing the slide, the slide is stopped 12 mm forward by a stopper.

The SUPERCATH 6 is available in 14G, 16G, 18G, 20G, 22G and 24G.

g. Indications for Use

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.

h. Statement of substantial equivalence

The SUPERCATH 6 is the modified version of the SUPERCATH 5 (K140419). The SUPERCATH 6 is intended to be used with power injectors. The intended use of the SUPERCATH 6 and the SUPERCATH 5 (K140419) differ only in the use for power injection.

Regarding the reference device, the SUPERCATH 6 has a similar intended use to the Introcan Safety® 3 Closed IV Catheter (K111236). Both devices act as an intravascular catheter for short term use (less than 30 days) and the same gauge sizes are suitable for use with power injectors at a maximum pressure of 300 psi.

The SUPERCATH 5 (K140419) and the SUPERCATH 6 have the identical needlestick injury prevention feature, flashback visualization system, side-notch needle, and reduction of blood exposure system.

The comparison table for technological characteristics among the SUPERCATH 6, the SUPERCATH 5 (K140419), and the Introcan Safety® 3 Closed IV Catheter (K111236) is shown below.

Comparison table for technological characteristics

Item	SUPERCATH 6	The predicate device; SUPERCATH 5 (K140419)	The reference device; Introcan Safety® 3 Closed IV Catheter (K111236)
Intended use	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.	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.	IIntrocan Safety® 3 Closed IV Catheter is inserted into a patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure or administer fluids and blood intravascularly. The 18-22 gauge catheters may be used with power injectors at a maximum pressure of 300 psi with a luer lock connection only.
Needlestick injury prevention feature	The metallic introducer needle is	The metallic introducer needle is	The passive safety needle-shielding

	retracted into the needle hub when the activation button on the needle hub is pressed.	retracted into the needle hub when the activation button on the needle hub is pressed.	mechanism of the Introcan Safety® 3 is located inside the catheter hub. Upon withdrawal of the needle, the safety shield engages as the needle passes through the catheter hub and deploys automatically to shield the needle tip.
Flashback visualization	Yes	Yes	Yes
Reduction of blood exposure	Yes (Check valve*[1])	Yes (Check valve*[1])	Yes (Septum)
Side-notch needle*[2]	Yes	Yes	No
Radiopaque	Yes	Yes	Yes
Use with power injectors	Yes (18-22 gauge)	No	Yes (18-22 gauge)
Sterilization	Ethylene oxide	Ethylene oxide	Ethylene oxide
Packaging	Tear-off pouch	Blister	Unknown
Multiple gauge sizes and needle length	Yes	Yes	Yes

Note:
*1: Check valve assists to reduce blood flashback when the metallic introducer needle is withdrawn following blood vessel puncture together with the healthcare professional's finger pressure.
*2: 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.

The modifications to the SUPERCATH 6 from the SUPERCATH 5 (K140419) include following changes of components and raw materials;

- All materials of the catheter hubs of the SUPERCATH 6 are different from those of the SUPERCATH 5 (K140419).
- The SUPERCATH 6 has the slide and the slide cap as new components
- Composition of the lubricating oil on the catheter of the SUPERCATH 6 is different from that of the SUPERCATH 5 (K140419).
- Formulation of the PVC of the SUPERCATH 6 is different from that of the SUPERCATH 5 (K140419)
- The SUPERCATH 6 does not have an attachment which the SUPERCATH 5 (K140419) has.

Following table is a brief comparison of main components and materials between the SUPERCATH

6 and the SUPERCATH 5 (K140419);

Comparison table for components and materials

Component name	Materials	
	SUPERCATH 6	SUPERCATH 5 (K140419)
Inner needle		
-Introducer needle	Stainless steel	Stainless steel
-Outer and Inner cover	Polycarbonate	Polycarbonate
-Needle hub	Polycarbonate	Polycarbonate
-Attachment	-	Polypropylene
-Slide	Polycarbonate	-
-Slide cap	Polypropylene	-
Catheter		
-Catheter tube	Polyurethane	Polyurethane
-Lubricating oil	Silicon	Silicon
-Catheter hub	Copolyester	Polycarbonate
-Wing	PVC	PVC

The attachment is used just during manufacturing process of the SUPERCATH 5 (K140419). The attachment is used in order to adjust the distance between the bevel of the introducer needle and the tip of the catheter. After the adjustment, the attachment is fixed and users cannot move the attachment. Although the SUPERCATH 6 does not have the attachment, the distance between the bevel of the introducer needle and the tip of the catheter is managed in our quality system. Therefore, the attachment does not affect substantial equivalence between the predicate device and the SUPERCATH 6.

Each gauge size of catheter hubs of the SUPERCATH 5 (K140419) and the SUPERCATH 6 is color-coded. However, all materials of the catheter hubs of the SUPERCATH 6 are different from those of the SUPERCATH 5 (K140419).

The SUPERCATH 6 has the slide and the slide cap as new components. User can choose to push the catheter hub forward or push the slide forward to insert the catheter. When pushing the slide, a stopper stops the slide 12 mm forward.

In order to evaluate any effects of the above changes on substantial equivalence, biocompatibility testing, sterilization validation, shelf-life testing, and performance testing were conducted. In conclusion, those testing demonstrated that the SUPERCATH 6 is substantially equivalent to the the SUPERCATH 5 (K140419).

i. Bench Testing

The following bench tests were performed to verify conformity to the recognized standards and demonstrate substantial equivalence to the SUPERCATH 5 (K140419).

- Tensile Strength for the Catheter

  The tensile strength of the catheter meets acceptable minimum force until breakage when tested according to ISO 10555-1.

- Air and Liquid Leakage for the Hub Attachment
  The catheter hub is impervious to air/liquid infiltration when subjected to positive pressure and aspiration when tested according to ISO 10555-1.
- Flow rate
  The flow rate through catheter meets allowable limits when tested according to ISO 10555-1.
- Power injection
  The catheter burst pressure exceeds the peak pressure present in the catheter at maximum flow conditions when tested according to ISO10555-1
- Leakage at the Check Valve under pressure
  The built-in check valve is impervious to liquid infiltration when subjected to positive pressure according to in-house standard.
- Tensile Strength for the Wing
  The tensile strength of the wing meets acceptable minimum force until breakage when tested according to in-house standard.

j. Biocompatibility Testing

Because the modifications to the SUPERCATH 6 from the SUPERCATH 5 (K140419) include changes of components and raw materials, we performed following biocompatibility tests;

- Cytotoxicity
- Sensitization
- Systemic (acute) toxicity
- Irritation/ Intracutaneous reactivity
- Pyrogenicity
- Implantation
- Subchronic and subacute systemic toxicity
- Genotoxicity
- Hemocompatibility
- Physicochemical tests

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

k. Simulated Clinical Use

The SUPERCATH 6 modified from the SUPERCATH 5 (K140419) has no new sharps injury prevention features. Therefore, this submission does not include the simulated clinical use testing report.

l. Conclusion

Based on the above discussion and enclosed sections regarding substantial equivalence to predicate device, TOGO MEDIKIT concludes that the SUPERCATH 6 is substantially equivalent to the SUPERCATH 5 (K140419).