APR 16 2012

Section 6- 510(k) Summary

a. Owner/Company name, address

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b. Contact/Application Correspondent

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c. Date prepared

July 20, 2011

d. Name of device

Trade Name:	SUPERCATH Z3V
Common Name:	Intravascular Catheter
Classification Name:	Catheter, Intravascular, Therapeutic, Short-term less than 30 days
Classification Regulation:	21 CFR 880.5200

e. Predicate devices

The SUPERCATH Z3V is substantially equivalent to the following legally marketed devices:

510(k):	k050114
Trade name:	SUPERCATH Z3V
Product code:	FOZ

510(k):	k093546
Trade name:	SUPERCATH 5
Product code:	FOZ

Since the same name as predicate device is used, the new device under application is hereinafter called "the SUPERCATH Z3V (PROPOSED)" and the predicate device is called "the SUPERCATH Z3V (k050114)" for convenience of discussion in this application

f. Description of the device

The SUPERCATH Z3V (PROPOSED) is an intravascular catheter and is available in following eight models.

1. with a check valve
2. with a wing
3. with a filter adapter
4. with a check valve and a wing
5. with a check valve and a filter adapter
6. with a wing and a filter adapter
7. with a check valve, a wing, and a filter adapter
8. without a check valve, a wing, or a filter adapter

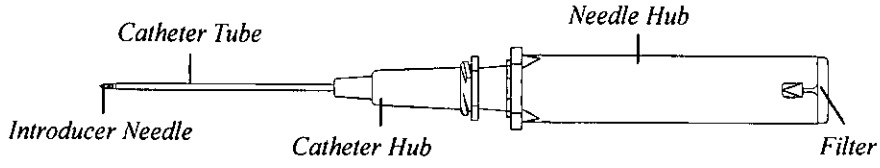
The SUPERCATH Z3V (PROPOSED) is intended to access a vein or artery and to administer fluids. The SUPERCATH Z3V (PROPOSED) is designed for single use, is intended for short-term use (less than 30 days), and is intended to minimize inadvertent needlesticks and to reduce accidental needlesticks by the safety system. In the safety system, the metallic introducer needle is retracted into the extendable needle casing.

The SUPERCATH Z3V (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finger pressure on the blood vessel, assists to reduce blood flashback when the metallic introducer needle is withdrawn following blood vessel puncture.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.

Some of the SUPERCATH Z3V (PROPOSED) has a filter adapter. The filter adapter can be removed and the SUPERCATH Z3V (PROPOSED) can be connected to a syringe in place of the filter adapter, under negative pressure and assist visual confirmation of blood access.

The SUPERCATH Z3V (PROPOSED) is available in 14G, 16G, 18G, 20G, 22G, and 24G.

Without Wing and Filter Adapter



g. Indications for Use

Indication for Use

The SUPERCATH Z3V (PROPOSED) is intended to access a vein or artery and to administer fluids. The SUPERCATH Z3V (PROPOSED) is designed for single use, is intended for short-term use (less than 30 days), and is intended to minimize inadvertent needlesticks and to reduce accidental needlesticks.

h. Statement of substantial equivalence

The SUPERCATH Z3V (PROPOSED) was essentially modified from the SUPERCATH Z3V (k050114). Thus, most of the characteristics of the SUPERCATH Z3V (PROPOSED) are similar to those of the SUPERCATH Z3V (k050114). The similarities are:

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

The SUPERCATH Z3V (PROPOSED) contains the following modifications as compared to the SUPERCATH Z3V (k050114):

- Change color additives for the catheter hubs
- Change the shape of a wing, a tab, and a protector for models with a wing
- Change the effective length of the catheter
- Change the unit container from a film bag to blister packaging

There is another predicate device for SUPERCATH Z3V (PROPOSED), which is the SUPERCATH 5 (k093546). Since the packaging (blister packaging) is identical between the SUPERCATH 5 (k093546) and the SUPERCATH Z3V (PROPOSED), the packaging test report for the SUPERCATH 5 (k093546) is used for the SUPERCATH Z3V (PROPOSED).

In order to evaluate biocompatibility for the SUPERCATH Z3V (PROPOSED), TOGO MEDIKIT performed biocompatibility tests. The test results did not raise biocompatibility concern.

For the difference of the catheter effective length, TOGO MEDIKIT performed "Flowrate test" to evaluate flow through the catheter. The test results were compliant with ISO standard as with using the SUPERCATH Z3V (k050114) and confirmed the difference does not raise safety and effective concern,

In order to evaluate overall effects of the above changes on safety and effectiveness, performance testing, sterilization validation, biocompatibility testing, simulated clinical study, and risk analysis were performed. In conclusion, those testing and analysis demonstrated that the above listed modifications did not raise any new safety or effectiveness concerns.

i. Risk Analysis

The SUPERCATH Z3V (PROPOSED) was evaluated in accordance with ISO14971:2007. The risk management of the device was deemed satisfactory.

j. Bench Testing

The following bench tests were performed to ensure the safety and effectiveness of the SUPERCATH Z3V (PROPOSED), verify conformity to the recognized standards and demonstrate substantial equivalence to the SUPERCATH Z3V (k050114).

- Tensile Strength for the Catheter
  The tensile strength of the catheter meets acceptable minimum force until breakage when tested according to ISO 10555-1.
- Tensile Strength for the Wing
  The tensile strength of the wing meets acceptable minimum force until breakage when tested according to in-house standard.
- 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 10555-5.
- 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.
- Leakage (Liquid) from vent fitting
  It was checked that the vent fitting (filter paper) is impervious to liquid infiltration when subjected to positive pressure when tested according to ISO 10555-5

All SUPERCATH Z3V (PROPOSED) samples were compliant with the ISO and in-house standards and demonstrated substantial equivalence to the SUPERCATH Z3V (k050114).

k. Biocompatibility Testing

As mentioned above, there is a change of color additives in the catheter hub between the SUPERCATH Z3V (PROPOSED) and the SUPERCATH Z3V (k050114). In order to evaluate biocompatibility for the SUPERCATH Z3V (PROPOSED), TOGO MEDIKIT performed following biocompatibility tests;

- Cytotoxicity
- Intracutaneous reactivity
- Delayed hypersensitivity
- Acute Systemic Toxicity
- Pyrogen test
- LAL test
- Leachable test

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

l. Sharps Injury Prevention Feature

In accordance with FDA's guidance "Medical Devices with Sharps Injury Prevention Features", Document issued on: August 9, 2005, TOGO MEDIKIT performed "Simulated Clinical Use of Study". Requirement in the statistical significant safety feature was confirmed for the sharp needle injury prevention feature of the SUPERCATH Z3V (PROPOSED).

m. Conclusion

The SUPERCATH Z3V (PROPOSED) has the same intended use, similar technological characteristics, components and materials as compared to predicates devices including the SUPERCATH Z3V (k050114) and the SUPERCATH 5 (k093546). Based on the information presented above regarding substantial equivalence, TOGO MEDIKIT concludes that the SUPERCATH Z3V (PROPOSED) is substantially equivalent to predicates devices including the SUPERCATH Z3V (k050114) and the SUPERCATH 5 (k093546) and does not raise any new questions regarding safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

TOGO MEDIKIT Company, Limited
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4-1-17 Hongo, Bunkyo-ku
Tokyo, 113-0033, Japan

APR 16 2012

Re: K112290
Trade/Device Name: SUPERCATH Z3V
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: March 2, 2012
Received: March 6, 2012

Dear Dr. 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 (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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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 yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): K112290

Device Name: SUPERCATH Z3V

Indication for Use

The SUPERCATH Z3V is intended to access a vein or artery and to administer fluids. The SUPERCATH Z3V is designed for single use, is intended for short-term use (less than 30 days), and is intended to minimize inadvertent needlesticks and to reduce accidental needlesticks.

Prescription Use X AND/OR Over-the Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for RZC Apr 13, 2012

(Division Sign-Off)

Division of Anesthesiology, General Hospital

Infection Control, Dental Devices

510(k) Number: K112290