K081953

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

January 30, 2009

d. Name of device

Trade Name:	SUPERCATH 5
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 5 is substantially equivalent to the following legally marketed devices:

510(k):	k013800
Trade name:	Insyte Autoguard™ IV Catheter
Product code:	FOZ

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

f. Description of the device

The device is an intravascular catheter known by the trade name SUPERCATH 5. It is available in two models, with a check valve and without a check valve.

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 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finger pressure on the blood vessel, assists to reduce blood flashback when the metallic introducer needle is withdrawn following blood vessel puncture.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 to prevent needlestick injury.

The SUPERCATH 5 is available in 18G, 20G, 22G and 24G.

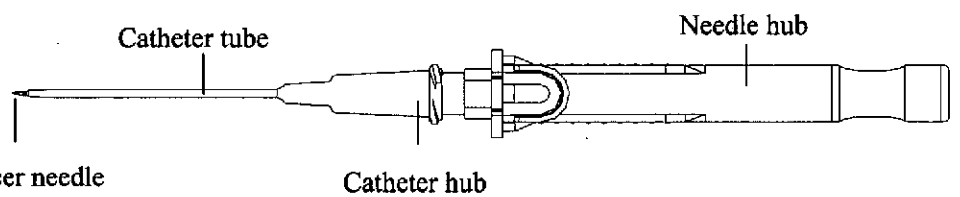

Figure 1. SUPERCATH 5

g. Indications for Use

Indication 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 for short-term use (less than 30 days), is designed to minimize inadvertent needlesticks and to reduce accidental needlesticks.

h. Statement of substantial equivalence

The characteristics of the SUPERCATH 5 are similar to those of the predicate devices described in Item e above. The similarities are:

- Same Intended Use
- Same Catheter Material (Polyurethane)
- Radiopaque
- Flashback Visualization
- Needle Stick Injury Prevention Feature
- Check Valve
- Ethylene Oxide Sterilized
- Single Sterile Wrapped
- Multiple Gauge Sizes and Needle Lengths

Table 1. Comparison of Factor/Component

Factor/Component	SUPERCATH 5	Insyte Autoguard™ IV Catheter (k013800)	Supercath Z3V (k050114)
Same Intended Use	Yes	Yes	Yes
Polyurethane Catheter	Yes	Yes	Yes
Radiopaque Catheter	Yes	Yes	Yes
Flashback Visualization	Yes	Yes	Yes
Needle Stick Injury Prevention Feature	Yes	Yes	Yes
Check Valve	Yes	No	Yes (hemostatic valve)
Ethylene Oxide Sterilized	Yes	Yes	Yes
Single Sterile Wrapped	Yes	Yes	Yes
Multiple gauge sizes and needle lengths	Yes	Yes	Yes
Used with power injectors up to 300 psi	No	Yes	No

The SUPERCATH 5 has the same intended use and similar technological characteristics as the "Insyte Autoguard™ IV Catheter" (k013800) and the "SUPERCATH Z3V" (k050114). Similar components and materials are used in the SUPERCATH 5 as in prior SUPERCATH models cleared for marketing by FDA.

i. Bench Testing

Bench tests were performed to ensure the safety and effectiveness of the SUPERCATH 5, conform to the recognized standards and to demonstrate substantial equivalence to the predicate device(s). All samples were compliant with the ISO and USP standards.

j. Simulated Clinical Use

In accordance with FDA's guidance "Medical Devices with Sharps Injury Prevention Features", Document issued on: August 9, 2005, the sharp needle injury prevention feature of the SUPERCATH 5 was tested.

The purpose of the Study was to test if the sharp needle injury prevention feature of the SUPERCATH 5 worked properly under a simulated use clinical environment. As per recommendation under the "Guidance", eight (8) health care professional volunteers who routinely use this type of catheter in their clinical practice were recruited.

The primary evaluation parameter was to test if the metal introducer needle completely retracted into the plastic needle hub after firmly pressing the safety button. This mechanism is the sharp needle injury prevention feature of the SUPERCATH 5.

No failures were observed in over 500 tests, under different test conditions and five (5) different catheter sizes of the SUPERCATH 5. Thus, the requirement of statistical significance of the safety feature was confirmed for the sharp needle injury prevention feature of the SUPERCATH 5.

k. Conclusion

Based on the above discussion and enclosed sections regarding substantial equivalence to predicate devices, TOGO MEDIKIT CO., LTD concludes that the SUPERCATH 5 is substantially equivalent to the "Insyte Autoguard™ IV Catheter" (k013800) and the "SUPERCATH Z3V" (k050114) and does not raise any new questions regarding safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2009

Togo Medikit Company, Limited
C/o Fumiaki Kanai, Ph.D.
President and CEO
MIC International
4/1/17 Hongo
Bunkyo-Ku, Tokyo 113-0035
JAPAN

Re: K081953
Trade/Device Name: SUPERCATH 5
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: January 30, 2009
Received: February 3, 2009

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K 081953

Indications for Use

510(k) Number (If known): K081953

Device Name: SUPERCATH 5

Indication 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 for short-term use (less than 30 days), is designed to minimize inadvertent needlesticks and to reduce accidental needlesticks.

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the Counter Use _____
(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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081953