DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 15, 2017

Acrostak (Schweiz) AG
Carmen Herraez
Clinical and Regulatory Affairs Manager
Stegackerstrasse 14
CH-8409 Winterthur
Switzerland

Re: K171176
Trade/Device Name: M-CATH Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, KRA
Dated: August 9, 2017
Received: August 17, 2017

Dear Carmen Herraez:

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 (DICE) 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) 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,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*

K171176

Device Name
M-CATH Microcatheter

Indications for Use *(Describe)*

The M-CATH Microcatheter is intended to provide support to the guide wire while performing PCI (percutaneous coronary intervention) and to facilitate the exchange of guide wires while maintaining access to distal vasculature. The device is also intended to deliver radiopaque contrast media into the coronary vasculature.

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

[as required by 21 CFR 807.92]

M-CATH™ Microcatheter

DATE PREPARED	**August 30th, 2017**
TRADE NAME	M-CATH™ microcatheter
COMMON NAME	Microcatheter
DEVICE CLASSIFICATION	Class II per 21 CFR §870.1250
PRODUCT CODE	DQY, Percutaneous Catheter

1. PREDICATE DEVICE

The predicate devices are Finecross® MG and Asahi Corsair, which are manufactured by Terumo Corporation and Asahi Intecc Co LTD, respectfully. The predicate devices have been cleared through the premarket notification process (Finecross® MG in K082519 and Asahi Corsair in K083127).

2. INTENDED USE

The M-CATH microcatheter is intended to provide support to the guide wire while performing PCI (percutaneous coronary intervention) and to facilitate the exchange of guide wires while maintaining access to distal vasculature. The device is also intended to deliver radiopaque contrast media into the coronary vasculature.

3. DEVICE DESCRIPTION

M-CATH™ consists of a catheter shaft, a hypotube and a hub. The catheter shaft has reinforcing braided mesh with high torquability. The outer surface of the catheter is coated with a hydrophilic polymer with a high lubricity upon moistening, hence, enhancing maneuverability and patient comfort.

The microcatheter has one distal radiopaque marker proximal at the distal tip.
The shaft has a central guidewire lumen which permits the use of a guide wire with maximum diameter of 0.014” (0.36 mm). The guidewire lumen begins at the proximal luer port and ends at the distal tip. At the proximal end the catheter has a hub with one port. The catheter is compatible with any 5F guiding catheter.

The main materials are stainless steel, PTFE and Pebax (braided shaft), stainless steel and Teflon (hypotube), Makrolon (luer), and Pt/Ir alloy (radiopaque marker). The coating is hydrophilic, based on hyaluronic acid.

4. PRINCIPLE OF OPERATION / TECHNOLOGY

M-CATH™ microcatheter is operated manually or by a manual process. The catheter should only be used by physicians trained in the performance of PCI.

5. SPECIFICATIONS

Usable length of catheter:	**135 cm**
Outer diameter of catheter (distal end):	2.25 Fr (0.75mm)
Outer diameter of catheter (middle):	3.30 Fr (1.10mm)
Outer diameter of catheter (proximal end):	2.10 Fr (0.70mm)
Inner diameter of catheter (distal end):	0.016" (0.40mm)
Inner diameter of catheter (proximal end):	0.018" (0.45mm)
Radiopaque markers:	1

6. PERFORMANCE DATA

Bench testing was performed on the M-CATH™ microcatheter to determine substantial equivalence. The following testing/assessments were performed:

1) Dimensional Verification
2) Ancillary Device Compatibility Test
3) Pushability and Trackability Testing
4) Catheter Bond Strength
5) Tip Pull Test
6) Flexibility and Kink Test
7) Torque Strength Test
8) Coating Lubricity
9) Particulate Evaluation – Coating Integrity
10) Particulate Evaluation – Coating Integrity (Coating Inspection)
11) Radiopacity
12) Maximum Labeled Pressure
13) Media Flow Rate

The in vitro bench tests demonstrated that M-CATH™ microcatheter met all acceptance criteria and performed similarly to the predicate devices. Performance data demonstrates that the device functions as intended, and is substantially equivalent to the predicate devices. The M-CATH™ microcatheter shelf life will be 3 years.

7. BIOCOMPATIBILITY TESTING

Blood contacting materials were tested in accordance with the test recommendations in International Standard ISO 10993, "Biological Evaluation of Medical Devices - Part I: Evaluation and Testing." The blood contacting materials were found to be biocompatible. The following biocompatibility and chemical characterization tests were performed:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity/Irritation
- Acute Systemic Toxicity
- Hemocompatibility
- Hematology: ASTM Hemolysis
- Complement Activation Assay (Sc5b9)
- In vivo thromboresistance
- Chemical Characterization

8. SUBSTANTIAL EQUIVALENCE

M-CATH™ microcatheter is substantially equivalent in intended use, principle of operation, technological characteristics, materials and performance to the Finecross® MG and Asahi Corsair, which are manufactured by Terumo Corporation and Asahi Intecc Co LTD, respectfully.

The submitted data demonstrates that the device is substantially equivalent as the legally marketed devices, and that the minor differences in materials and design do not raise different questions of substantial equivalence to the predicate devices.

9. SUBMITTER INFORMATION

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