DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 18, 2016

Mercator MedSystems, Inc.
% Adam Harris
Associate Director, Regulatory Affairs
Target Health Inc.
261 Madison Ave
24th Floor
New York, NY 10016

Re: K161402
Trade/Device Name: Bullfrog Micro-Infusion Device
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: May 17, 2016
Received: May 20, 2016

Dear Adam Harris:

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" (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 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,

Brian D. Pullin -S

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)*
K161402

Device Name
Mercator MedSystems Bullfrog® Micro-Infusion Device

Indications for Use *(Describe)*
In selective areas of peripheral and coronary vessels, the Bullfrog Micro-Infusion Device is intended for the infusion of diagnostic and therapeutic agents into the vessel wall and perivascular area, or intraluminally.

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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5. 510(K) SUMMARY

510(k) Applicant
Mercator MedSystems, Inc.
1900 Powell Street, Suite 800
Emeryville, CA 94608
Telephone: (510) 614-4550
Facsimile: (510) 614-4560

Contact Person: Adam Harris, Target Health
Phone: (646) 218-2009
Email: aharris@targethealth.com

Date of Summary: 9 May 2016

Device Overview
Trade Name: Bullfrog® Micro-Infusion Device

Common Name: Continuous Flush Infusion Catheter (per 21 CFR 870.1210)

Classification: Continuous Flush Infusion Catheter
21 CFR 870.1210
Product Code KRA
Panel: Cardiovascular

Predicate Device

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K153501	Bullfrog® Micro-Infusion Device	Mercator MedSystems

Reference Devices

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K140637	Peregrine System Infusion Catheter	Ablative Solutions
K062752	MicroSyringe II/Bullfrog Micro-Infusion Device	Mercator MedSystems

Device Description
The Mercator MedSystems Bullfrog Micro-Infusion Device is a wire-guided, single-operator, endovascular catheter that consists of a perpendicular microneedle, which is sheathed by and contained within a semi-rigid polymer actuator balloon. The device is designed to be advanced to target vasculature and hydraulically actuated to move the microneedle through the external elastic lamina to deliver substances to adventitial and

perivascular tissues. A compliant stabilizing balloon inflates with the actuator to provide a force opposite the needle tip for proper seating of the needle. The needle is retracted within the sheathing structure by vacuuming the hydraulic actuator.

Indications for Use
In selective areas of peripheral and coronary vessels, the Bullfrog Micro-Infusion Device is intended for the infusion of diagnostic and therapeutic agents into the vessel wall and perivascular area, or intraluminally.

Technological Characteristics
All materials used in the manufacture of the Bullfrog Micro-Infusion Device are suitable for this use and have been used in several previously cleared products.

Performance Data
No new performance testing was conducted to support substantial equivalence, since the predicate and subject devices are identical in terms of technological characteristics. Performance testing of the predicate device included mechanical and fluid delivery performance, biocompatibility, sterilization validation, in-vivo safety and effectiveness studies. All tests met the pre-determined specifications and acceptance criteria.

Safety and Effectiveness
The Bullfrog Micro-Infusion Device labeling contains instructions for use and any necessary cautions and warnings to assure safe and effective use of the device. The biocompatibility assessment was conducted in accordance with ISO 10993, Biological Evaluation of Medical Devices.

Comparison to Predicate Devices
Aside from the change in the Indications for Use, the Bullfrog Micro-Infusion Device is identical in design and performance to the predicate. The Bullfrog Micro-Infusion Device is also substantially equivalent to the reference devices. Both the predicate device and one of the reference devices, the Peregrine System Infusion Catheter (K140637), relied on the predicate of the other reference device, the MicroSyringe II/Bullfrog Micro-Infusion Device (K062752).

The Bullfrog Micro-Infusion Device is available in three model sizes (2-4 mm, 3-6 mm and 4-8 mm), which is identical to the predicate. Risk analysis has shown that the Bullfrog Micro-Infusion Device has the same risk profile as the predicate.