August 2, 2021

Mercator MedSystems, Inc.
Kirk Seward
President and Chief Science & Technology Officer
1900 Powell Street
Suite 800
Emeryville, California 94608

Re: K210339
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: June 29, 2021
Received: July 1, 2021

Dear Kirk Seward:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210339

Device Name
Bullfrog Micro-Infusion Device

Indications for Use *(Describe)*

For Bullfrog devices capable of treating <6 mm diameter vessels:
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.

For Bullfrog devices capable only of treating ≥6 mm diameter vessels:
In selective areas of peripheral vessels, the Bullfrog Micro-Infusion Device is intended for 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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K210339 510(K) SUMMARY

510(k) Applicant
Mercator MedSystems, Inc.
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Telephone: (510) 614-4550
Facsimile: (510) 614-4560

Contact Person: Monica Barrett
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Date of Summary: 20 April 2021

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
K161402	Bullfrog® Micro-Infusion Device	Mercator MedSystems

Reference Devices

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K153501	Bullfrog® Micro-Infusion Device	Mercator MedSystems
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
For Bullfrog devices capable of treating <6 mm diameter vessels:
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.

For Bullfrog devices capable only of treating ≥6 mm diameter vessels:
In selective areas of peripheral vessels, the Bullfrog Micro-Infusion Device is intended for 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
Performance testing of the Bullfrog Micro-Infusion Device included mechanical and fluid delivery performance, biocompatibility, sterilization validation, and in-vivo safety studies. All tests met the pre-determined specifications and acceptance criteria.

The Bullfrog Micro-Infusion Device labeling contains instructions for use and any necessary cautions and warnings to assure that there are no new questions of safety and effectiveness with use of the device compared to the predicate. The biocompatibility assessment was conducted in accordance with ISO 10993, Biological Evaluation of Medical Devices.

Comparison to Predicate and Reference Devices
The Bullfrog Micro-Infusion Device is available in 5 models, each having a specified operating diameter range and in total spanning from 2 mm to 16 mm operating diameter. The predicate and reference devices span the range from 2 mm to 50 mm operating diameter. Notably, the Rex Medical Quadra-Fuse™ Multi-pronged Injection Needle, which is 510(k) exempt, is a multi-needle device with larger diameter needles than the Bullfrog device and is indicated for infusion and aspiration of fluids with ability to target up to 50 mm diameter tissue zone. Reference devices utilizing various grades of Pebax® including 40D and 72D durometer were provided as evidence of Pebax® material biocompatibility.

The following changes to the Bullfrog device were implemented since K161402 clearance.

1. External laser-cut steel hypotube replaced the internal bonded wire to provide torque control.

2. An additional device (BF102R) was added to the product family with the same operating diameter as prior model BF102S (2-4mm), but smaller crossing profile for smaller introducer sheath and guide catheter compatibility.
3. Manufacturing method changes were verified.
4. Re-ordering of manufacturing processes.
5. Addition of BF102P to the Bullfrog product family.
6. Updates to Instructions for Use.
7. Intended Use and Indications for Use identical to K161402, but without allowance for coronary use for devices intended to operate only in vessels with 6mm or larger diameter.

Non-Clinical Performance Data

Biocompatibility testing was adopted from prior versions of the device (K161402) since there were no material changes and the changes in percent composition of the complete device were determined to be insignificant. Non-clinical testing of components of the device that have changed since K161402 included functional testing as defined in ISO 10555-1 with Amendments 1 and 2, and customized testing for performance. Testing performed on the device included:

- Sterilization testing per ISO 11137-1:2006 and ISO 11137-2:2013
- Distribution testing per ASTM D4169
- Pouch bubble testing per ASTM F2096
- Pouch seal strength testing per ASTM F88/F88M
- Label adhesion
- System fluid delivery rate
- Catheter stiffness
- Actuator inflation and deflation time
- Actuator diameter minimum/maximum
- Actuator integrity after tortuous anatomy
- Actuator burst strength
- Drug line integrity
- Drug line burst strength
- Inflation line leakage under vacuum
- System leakage under pressure
- Pressure relief valve cracking pressure and leak rate
- Radio-opaque markers intact
- Microneedle sheathing
- Microneedle insertion force at failure
- Microneedle durability
- Microneedle active length
- Actuator retraction force to failure and in vacuum
- Catheter bend kink resistance
- Tensile strength
- Torsional strength
- Repetitive function and fatigue

Conclusions

The Bullfrog Micro-Infusion Device is substantially equivalent to the predicate and reference devices. Risk analysis has shown that the Bullfrog Micro-Infusion Device has the same risk profile as the predicate.