June 10, 2022

Smartwise Sweden AB
Maria Nordlinder
QA/RA Manager
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Sweden

Re: K213442/S001
Trade/Device Name: Extroducer Infusion Catheter System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: May 2, 2022
Received: May 5, 2022

Dear Maria Nordlinder:

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,

for

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)*
K213442

Device Name
Extroducer Infusion Catheter System

Indications for Use *(Describe)*
The Extroducer Infusion Catheter System is intended for infusion of diagnostic or therapeutic solutions into the perivascular area of the peripheral vasculature. The Extroducer Infusion Catheter System is also intended for the infusion of diagnostic and therapeutic solutions 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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510(k) Summary
K213442

Date prepared: June 07, 2022

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1 Device Information

Trade Name: Extroducer™ Infusion Catheter System
Regulation number: 21 CFR 870.1210
Regulation name: Continuous flush catheter
Product code: KRA
Class: II

1.1 Predicate Device:

Bullfrog® Micro-Infusion Device, manufactured by Mercator MedSystems, Inc. (K161402)

2 Device description

The Extroducer™ Infusion Catheter System is a minimally invasive device for administering diagnostic or therapeutic solutions through the vascular wall directly to perivascular tissue of adult patients. At the selected site, the device is used to penetrate through the vascular wall into the tissue requiring treatment. The diagnostic or therapeutic solution is then delivered through the device.

The device is sterile and designed for single patient use only. The device is to be used in hospital operating theaters and catheterization labs under normal clinical conditions, only by physicians trained in its use. The duration of use is no more than 60 minutes.

The Extroducer™ Infusion catheter system consists of two main parts:
- An infusion needle with a needle hub and radiopaque marker
- An outer protective sheath to protect the needle during positioning of the device, with a haemostatic valve to secure the infusion needle during use

The package also includes the following accessories, which are optional to use:
- A 0.25 mL syringe with a male Luer lock
- A dispensing tip to aid in the flush of the outer protective sheath

Additional accessories, not covered by this submission, includes:
- Guide catheters with a minimum ID of 0.021”
- Additional syringes 0.25-1.0 mL, male Luer lock (one syringe included in package)

During the procedure, the needle is inserted into the outer protective sheath, secured in place with the haemostatic valve, then the device is fed through a guide catheter, prepositioned inside the vessel, to the selected site of treatment. Once in place the needle is released and manually moved forward out of the outer protective sheath through the vessel wall, and into the perivascular tissue. The radiopaque marker band near the distal tip of the needle provides for visualization of the needle under fluoroscopy and also functions as a depth limiting collar.

2.1 Models

The Extroducer™ Infusion Catheter system is available in three models, see Table 1, each with the radiopaque marker band/depth limiting collar positioned at different lengths from the infusion needle distal tip: 5mm, 10mm and 15mm, enabling penetration of tissue at different depths. Aside from the position of the radiopaque marker band/depth limiting collar, the models are identical.

Table 1 Available models of the Extroducer™ infusion catheter system

Name	**Article number**	**Penetration depth (mm)**
Extroducer™ infusion catheter system	200101-5	5
Extroducer™ infusion catheter system	200101-10	10
Extroducer™ infusion catheter system	200101-15	15

2.2 Indications for Use

The Extroducer™ Infusion Catheter System is intended for infusion of diagnostic or therapeutic solutions into the perivascular area of the peripheral vasculature. The Extroducer™ Infusion Catheter System is also intended for the infusion of diagnostic and therapeutic solutions intraluminally.

2.3 Technological characteristics

The Extroducer™ Infusion Catheter System has a manual deployment method and compared to the predicate device do not use a balloon or hydraulic system. The subject device has been tested to verify functionality and safety and is therefore considered substantially equivalent to the predicate device. See Table 2 for details.

Table 2 Comparison of Predicate device and Subject device

Item	**Subject device – Extroducer Infusion Catheter System**	**Predicate device – Bullfrog® Micro-Infusion Device (K161402)**	**Comparison**
Indications for use	The Extroducer Infusion Catheter System is intended for infusion of diagnostic or therapeutic solutions into the perivascular area of the peripheral vasculature. The Extroducer Infusion Catheter System is also intended for the infusion of diagnostic and therapeutic solutions intraluminally.	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.	Same for the peripheral vasculature, although not identically phrased; coronary vessels excluded for the subject device.
Design	Infusion needle with radio-opaque markers and a luer port, placed inside a protective sheath.	Catheter with a perpendicular microneedle, which is sheathed by and contained within a balloon, which upon inflation provide a force opposite the needle tip for proper seating of the needle.	There are differences in the designs of the subject and predicate devices; however, they do not raise different questions of safety and effectiveness (S&E.)
Needle deployment method	Manual deployment by physician.	Inflation of balloon attached the needle.	There are differences in the needle deployment of the subject and predicate devices; however, they do not raise different questions of S&E.
Catheter length	179cm (from needle hub)	145 cm (not including handle)	The difference in length of the catheters does not raise different questions of S&E.
Needle length	5-15 mm from radiopaque marker/depth limiting collar (Three models: 5, 10, 15 mm)	0.9 mm	Possible to insert the subject device needle further into the tissue; however, this does not raise different questions of S&E.
Outer diameter	0.5 mm (Sheath)	1.65 – 1.75 mm (balloon location)	The difference in diameter of the catheters does not raise different questions of S&E.

Needle diameter (OD)	0.19 mm	34 G (0.18 mm)	Same
Target vessel diameter	2-8 mm	2-8 mm	Same
Biocompatibility	Tested according to ISO 10993	Tested according to ISO 10993	Same
Number of uses	Single patient use	Single patient use	Same
Sterility	Provided sterile	Provided Sterile	Same
Shelf Life	1 year	Not available	Possibly different shelf life; however, this does not raise different questions of S&E.
Radio-opaque markers	Yes	Yes	Same

3 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

3.1 Non-clinical performance data

The following tests have been conducted:

- Dimensional verification of catheter
- Simulated use (including trackability)
- Catheter bond strength
- Flexibility and kinking
- Torque strength
- Radiopacity
- Particulate evaluation
- Catheter body burst pressure
- Infusion flow rate
- Visual inspection
- Needle characteristics (tensile strength, tip strength etc.)
- Functional testing of Thumb wheel/haemostatic valve
- Leakage testing
- Infusion force
- Biocompatibility (according to ISO 10993):
    - Cytotoxicity
    - Sensitization
    - Intracutaneous Reactivity
    - Systemic Toxicity, including Acute Systemic Toxicity and Material Mediated Pyrogenicity
    - Hemocompatibility, including direct and indirect hemolysis, Complement activation assay and In vivo thrombogenicity
- Sterilization validation
- Transport testing

- Package testing (sterile barrier)
- Stability studies (selected bench tests and package tests)

3.2 Animal testing

An animal study has been performed in order to evaluate the safety of the subject device compared to the predicate device. It was concluded that the Extroducer™ Infusion Catheter System was able to be navigated to all intended target arteries. The results from the treatment procedures, performance assessments, thrombosis evaluation of the device, gross pathology, histopathology, and clinical pathology assessments support the conclusions of safety of the intended clinical use of the Extroducer™ Infusion Catheter System.

3.3 Clinical data

No clinical studies have been performed. Available non-clinical bench performance testing data, animal and biocompatibility studies are considered sufficient to support a substantial equivalence determination.

4 Conclusions

The results of the non-clinical tests described above demonstrate that the Extroducer™ Infusion Catheter System is substantially equivalent to the predicate device.