

ABLATIVE SOLUTIONS

510(K) SUMMARY (21 CFR 807.92)

ABLATIVE SOLUTIONS, INC. PEREGRINE SYSTEM™ INFUSION CATHETER

510(k) Owner: Ablative Solutions, Inc.
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Date Prepared: February 2014

Trade Name: Peregrine System™ Infusion Catheter

Common Name: Continuous flush catheter

Classification Name: Continuous flush catheter per 21 CFR 870.1210, KRA

Predicate Devices: Mercator MicroSyringe II Infusion Catheter K062752
Rex Medical Quadra-Fuse Multi-pronged Injection Needle (exempt)

Device Description: The Peregrine System Infusion Catheter is a percutaneous catheter designed to deliver diagnostic and therapeutic agents through a vessel wall and into the perivascular space. The catheter contains three distal needles which are deployed using the control handle. Fluids are administered through the proximal injection lumen in the handle, which delivers the fluid through the needles at the distal end of the device. The micro-needles and the guide tubes are radiopaque for fluoroscopic visibility. The device is intended for vessels 5-7 mm in diameter and is compatible with guide catheters of at least 7F.

Indications for Use: The Peregrine System Infusion Catheter is intended for the infusion of diagnostic and therapeutic agents into the perivascular area of the peripheral vasculature.

The indications are substantially equivalent to the indications for the Mercator MedSystems MicroSyringe II Infusion Catheter. The MicroSyringe II is additionally indicated for use in the coronary vessels and for injection of diagnostic and therapeutic agents that are indicated for delivery into the vessel wall.

Technological
Characteristics:

The Peregrine System Infusion Catheter has three equally circumferentially spaced needles which deliver a diagnostic or therapeutic agent to a pre-specified depth by actuating the handle. A fluid can therefore be delivered to the perivascular area with complete circumferential coverage using a single injection. The needles are advanced mechanically from the handle.

The technological characteristics are comparable to the predicate device, which delivers drugs through a single micro-needle to a pre-specified depth. The micro-needle in the predicate device punctures the vessel wall using the force of a balloon at the distal end of the catheter. Multiple, circumferential micro-needle technology also exists in commercially available injection needles, which are 510(k) exempt.

The technological characteristics of the Peregrine System Infusion Catheter are comparable to the predicate device, and can be validated with bench testing. There are no technological differences which could raise new questions of safety or efficacy.

Non-Clinical
Performance Data:

Non-clinical testing included biocompatibility testing of the assembled device as defined in ISO 10993, functional testing as defined in ISO 10555-1 with Amendments 1 and 2, and customized testing for performance. Testing performed on the proposed device included:

- Visual/Dimensional Inspection
- Air Ingress/Negative Collapse
- Tensile Strength
- Liquid Leakage under Pressure/Leakage at Hub
- Flexibility and Kink
- Tip Stiffness
- Guide Tube Deployment Force
- Catheter Torque
- Guidewire Torque
- Corrosion Resistance
- Chemical Compatibility
- Simulated Use Testing
- Biocompatibility:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous
- Acute systemic toxicity
- Materials mediated pyrogenicity
- Hemocompatibility – hemolysis by direct contact
- Hemocompatibility – hemolysis by extract
- Complement activation of C3a and SC5b-9
- Thrombogenicity in Sheep
- Packaging/Simulated Shipping Testing
- Sterilization validation
- *In-vivo* testing

Conclusions:

The non-clinical bench testing, simulated-use testing and *in-vivo* testing demonstrate that the Peregrine System Infusion Catheter functions as intended, meets the requirements of ISO 10555-1, and performs equivalent or better than the predicate device. The testing supports a determination of substantial equivalence to products previously cleared by FDA.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 26, 2014

Ablative Solutions, Inc.
c/o Sharon Rockwell
Regulatory Affairs Consultant
801 Hermosa Way
Menlo Park, CA 94025

Re: K140637

Trade/Device Name: Peregrine System™ Infusion Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: February 26, 2014
Received: March 12, 2014

Dear Ms. Rockwell:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K140637

Device Name: Peregrine System™ Infusion Catheter

Indications for Use: The Peregrine System is intended for the infusion of diagnostic and therapeutic agents into the perivascular area.

Prescription Use X
(Part 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 IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S

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