July 5, 2023

Ablative Solutions, Inc.
Kristine Canavan
VP, Regulatory & Quality
301 Edgewater Place
Suite 100
Wakefield, Massachusetts 01880

Re: K231279
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: May 2, 2023
Received: May 3, 2023

Dear Kristine Canavan:

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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2023.07.05 15:55:58 -04'00'

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)*
K231279

Device Name
Peregrine System™ Infusion Catheter

Indications for Use *(Describe)*
The Peregrine System™ Infusion Catheter is intended for the infusion of diagnostic and therapeutic agents into the perivascular area of the peripheral 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY (21 CFR 807.92)

ABLATIVE SOLUTIONS, INC.
PEREGRINE SYSTEM™ INFUSION CATHETER

510(k) Owner: Ablative Solutions, Inc.
301 Edgewater Place • Suite 100
Wakefield, MA 01880
United States

Contact Person: Kristine Canavan
Vice President, Regulatory & Quality
Phone: (617) 877-7953
Email: kcanavan@ablativesolutions.com

Date Prepared: July 5, 2023

Device Information

Trade Name:	Peregrine System™ Infusion Catheter
Common Name:	Continuous Flush Catheter
Classification Name:	Continuous Flush Catheter
Product Code:	KRA
Regulation Number:	21 CFR 870.1210
Predicate Device:	Peregrine System™ Infusion Catheter (K140637)

Device Description:
The Peregrine System Infusion Catheter is a continuous flush 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 3-7 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 indication for use is identical to the indication for use of the predicate device, Peregrine System Infusion Catheter. Both catheters are indicated for use in peripheral vessels for infusion of diagnostic and therapeutic agent into the perivascular space.

Technological Characteristics:
The Peregrine System Infusion Catheter continues to have three equally circumferentially spaced micro-needles set inside guide tubes. The guide tubes stabilize the catheter within the vessel prior to deploying the micro-needles through the vessel wall. The micro-needles penetrate into the perivascular space at a pre-specified depth. Both the guide tubes and the micro-needles are mechanically deployed by actuating the handle prior to delivering the infusate. The infusate is delivered into the perivascular area in a circumferential pattern with a single injection. The catheter is provided sterile and is intended for single patient use.

The technological characteristics of the Peregrine Catheter remain similar to that of the predicate device, except for use in vessels having an inner diameter of 3-7 mm. The design modifications to permit use of the Peregrine Catheter in vessels having an inner diameter of 3-7 mm are limited to the design of the guide tube (length, angle) and the travel length of the deployment feature within the handle. The technological characteristics of the subject Peregrine System Infusion Catheter can be validated with non-clinical testing. There are no technological differences which could raise new questions of safety or efficacy.

Non-Clinical Performance Data:
There were no changes to materials and design for the Peregrine Catheter for use in vessels having an inner diameter 4-7 mm. Changes to the Peregrine Catheter for use in vessels having an inner diameter 3-4 mm were limited to the smaller guide tube open diameter, including the guide tube length, guide tube angle, and the travel length of the deployment feature within the handle. These modified design features were incorporated to preserve the same safety, performance and functionality as that present in the Peregrine Catheter predicate device.

Design testing for the Peregrine Catheter included:
Visual Inspection
Dimensional Testing (length, diameter)
Performance (tensile, leak)
Functional (kink radius, deployment force, simulated use, stiffness, torque, leak)
Pre-Clinical Animal Safety Study

Materials testing, packaging testing, and sterilization testing were not impacted by the design modifications for use of the Peregrine Catheter in vessels having an inner diameter 3-7 mm.

Conclusions:
The non-clinical bench testing, simulated-use testing and pre-clinical animal safety testing demonstrate that the Peregrine System Infusion Catheter functions as intended and is suitable for use in vessels having an inner diameter of 3-7 mm while being substantially equivalent to the predicate device.