Upstream Peripheral Technologies, Ltd.
% Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K182937
Trade/Device Name: Upstream GoBack Crossing Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: April 22, 2019
Received: April 22, 2019

Dear Janice Hogan:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lydia S. Glaw -S
Digitally signed by Lydia S. Glaw -S
Date: 2019.05.23 13:58:49 -04'00'

for Kenneth Cavanaugh, Ph.D.
Director (Acting)
DHT2C: Division of Coronary and Peripheral Interventional Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

The Upstream GoBack Crossing Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires.

The Upstream GoBack Crossing Catheter is not intended for use in the coronary, cerebral or carotid 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.

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

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Applicant Information

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Date Prepared: May 22, 2019

Device Information

Trade Name: Upstream GoBack Crossing Catheter
Common or Usual Name: Catheter for Crossing Total Occlusions
Classification: Class II per 21 CFR 870.1250
Product Code: PDU
Predicate Device: Cordis Outback Catheter (K001577)
Reference Device: ReFlow Wingman Crossing Catheter (K151880)

Intended Use / Indications for Use

The Upstream GoBack Crossing Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires.

The Upstream GoBack Crossing Catheter is not intended for use in the coronary, cerebral or carotid vasculature.

Device Description

The Upstream GoBack Crossing Catheter is a sterile, single-use, single lumen support catheter, that consists of a reinforced polyimide shaft with a stainless steel tip, and PTFE polymer coated nitinol hypotube inside the shaft. The nitinol tube has a pre-shaped lancet tip at the distal end and a hub at the proximal end for guidewire access. The nitinol tube can move at limited displacement inside the shaft, by moving a sliding knob in the catheter handle.

The Upstream GoBack Crossing Catheter is intended for use with 0.014” and 0.018” non-coated guidewires and the effective length of the catheter is 120 cm with an outer diameter of 1.4 mm.
Comparison of Technological Characteristics

The GoBack Catheter, the OutBack catheter and the Wingman Crossing Catheter have very similar technological features. Each of the devices is a single-lumen, sterile, single-use catheter comprised of biocompatible materials. The GoBack Catheter, the OutBack catheter and the Wingman Crossing Catheter shafts are composed of braided polymer tubes of three layers - a middle layer composed of metal stainless steel wires, with an outer polymer jacket and an inner polymer liner. A slide-able flexible metal tube is located inside the shaft of all devices. Further, the GoBack Catheter, the predicate and reference devices all incorporate a distal lancet tip of the slide-able metal tube, and proximal female luer hub. The slide-able metal tubes are coated with PTFE or Teflon coating to permit smooth tracking of the metal tube inside the shaft.

Although there are minor differences between the GoBack Catheter and the predicate device, none of these differences raise new types of safety or effectiveness questions. The GoBack Catheter needle tip is curved with a maximal needle tip protrusion of 11 mm whereas the predicate device consists of a curved needle tip with a maximal tip protrusion of 8 mm. This difference does not raise new questions of safety or effectiveness as both devices consist of adequate device mechanisms for device needle navigation through the peripheral vasculature, which has been confirmed by bench testing.

The GoBack Catheter radiopaque marker is mounted directly on the needle and serves to identify the needle tip location and needle curve direction, while the predicate’s similar radiopaque marker is mounted on the catheter shaft and serves to identify only the needle curve direction. This minor technological difference does not raise new issues of safety or effectiveness because the key question of device detection using radiopaque markers during clinical procedures is the same for both the subject and predicate device.

The dimensions of the GoBack Catheter are within the range of dimensions of the predicate. The GoBack Catheter is 120 cm in length. The OutBack catheter length is 80 cm and 120 cm, while the Wingman Crossing Catheter is available in several length sizes, including 65 cm, 90 cm, 135 cm, and 150 cm. The outside diameter of the GoBack Catheter is 1.4 mm, the OutBack catheter diameter is 2.0 mm, and the Wingman catheter has outside diameters of 1.3-1.5 mm. Thus, the dimensions of the GoBack Catheter do not raise new types of safety or effectiveness questions because the length and outside diameter of the GoBack Catheter are within the range of dimensions of the cleared predicate and reference devices.

Furthermore, all verification testing conducted with the GoBack Catheter demonstrates that the device meets its intended design and performance specifications, and that minor differences in technological features do not impact safety or effectiveness. Therefore, any minor technological differences do not raise new questions of safety or efficacy of the device and it satisfies the second criterion for substantial equivalence based on the technological characteristics compared to the predicate device.

Performance Testing Summary

The following nonclinical performance testing has been conducted to support the substantial equivalence of the Upstream GoBack Crossing Catheter to its predicate device. In all instances, the Upstream GoBack Crossing Catheter functioned as intended.

- Sterilization validation was established in accordance with ISO 11135 and EN 868-5.

- Packaging integrity and accelerated aging studies were completed in accordance with ISO 11607-1, ISO 11607-2, ASTM F1980-07, and ASTM F1929.
• Biocompatibility of the patient-contacting components of the device was established in accordance with ISO 10993-1 and included cytotoxicity, sensitization, irritation/intracutaneous reactivity, systemic toxicity (acute), hemocompatibility (hemolysis and thromboresistance), pyrogenicity, and complement activation.

• Functional bench testing was conducted on sterile devices (air leakage test, liquid leakage test, force at break test, surface test, catheter dimensions test, catheter delivery and kink testing, catheter torque testing, needle tip protrusion testing, marker movement test, torque at break test, bending to kink test, transfer of torsional force, needle penetration force catheter radio-opaque testing, corrosion testing, catheter hydration testing, catheter environmental testing, and packaging sealing testing).

In addition, a retrospective evaluation of 25 subjects was conducted based on clinical cases performed at Leipzig University Medical Center and at Bad-krozingen Heart-Center, both in Germany, to provide additional clinical data regarding the safety and technical success of the GoBack Catheter for recanalization of chronic total occlusion (CTO) in the iliac/femoropopliteal arteries.

Study subjects were required to have claudication or critical limb ischemia (Rutherford Category 2-5) and a de novo or re-occluded CTO (99-100%) lesion in a native iliac/femoropopliteal artery. The indication for intervention in these cases included claudication and critical limb ischemia. In all cases, conventional recanalization could not be successfully achieved.

The primary safety endpoint was a composite rate of major adverse endpoints events (MAEs) related to the GoBack Catheter through 24 hours post index procedure including: death, perforation requiring intervention and clinically significant peripheral embolism. The primary effectiveness endpoint was device technical success, defined as the placement of a guidewire in the true lumen distal to a CTO as confirmed by the angiography core lab.

Of the subjects enrolled, 20 of 25 (80%) were male. The average age was 67 ± 10 years (range: 39 – 82). The average lesion length was 21 ± 12 cm (range: 4 – 55). Investigators achieved a 92% percent (23/25) technical success rate using the GoBack Catheter to cross CTOs in the iliac/femoropopliteal arteries. At 24 hours post procedure (pre-discharge), all patients experienced an improvement of at least one category in the Rutherford classification, a six-stage scale commonly used to assess the severity of symptoms associated with PAD. No device-related adverse event was seen during the procedures or at 24 hours post procedure. These results support the substantial equivalence of the GoBack Crossing Catheter

Substantial Equivalence

The Upstream GoBack Crossing Catheter and the predicate device have the same intended use and very similar indications, technological characteristics and principles of operation. The minor technological differences between the Upstream GoBack Crossing Catheter and its predicate raise no new types of safety or effectiveness questions. Performance testing demonstrates that the Upstream GoBack Crossing Catheter performs as intended and meets all design specifications with respect to its mechanical and handling characteristics, and that its materials are biocompatible. Thus, the Upstream GoBack Crossing Catheter is substantially equivalent to the Cordis Outback Catheter predicate device.