March 1, 2022

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

Re: K211802
Trade/Device Name: GoBack Crossing Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: January 27, 2022
Received: January 27, 2022

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/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 Lydia Glaw
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)*
K211802

Device Name
Upstream GoBack Crossing Catheter

Indications for Use *(Describe)*
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.

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510(k) SUMMARY

Upstream Peripheral Technologies Ltd's GoBack Crossing Catheter

Applicant Information:

Upstream Peripheral Technologies Ltd.
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P.O. Box 3067
43 Haeshel Street
Caesarea 38900
Israel

Phone: (972) 4-6239014
Facsimile: (972) 4-6273260
Contact Person: Dan Rottenberg
Date Prepared: March 1, 2022

Device Information:

Trade Name:	Upstream GoBack Crossing Catheter
Common or Usual Name:	Percutaneous Catheter
Classification:	Class II per 21 CFR 870.1250
Product Code:	PDU
Predicate Device:	Upstream GoBack Crossing Catheter (K182937)
Reference Device:	Cord is Outback Catheters (K001577 / K150836)
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 crossing catheter.

The Upstream GoBack Crossing Catheter is intended for use with 0.014" and/or 0.018" coated or non-coated guidewires. The effective length of the GoBack Crossing Catheter is 80 cm or 120 cm with an outer diameter of either 0.96 mm (2.9 Fr) or 1.4 mm. (4.0 Fr). The table below shows the 4 models of the device.

GoBack Crossing Catheter: 4 Models

GoBack Crossing Catheter Description	Model Number
2.9 Fr, 80 cm GoBack Crossing Catheter	GB 603 014 80L
2.9 Fr, 120 cm GoBack Crossing Catheter	GB 603 014 120L
4 Fr, 80 cm GoBack Crossing Catheter	GB 600 018 80L
4 Fr, 120 cm GoBack Crossing Catheter	GB 600 018 120L

The GoBack Crossing Catheter is made from three layers; a reinforced polyimide shaft with stainless steel distal tip (in the 2.9 Fr device) or stainless steel and Nylon 12 distal tip (in the 4.0 Fr device), nitinol hypotube, and PTFE polymer sleeve over the nitinol hypotube inside the shaft. The nitinol hypotube has a pre-shaped curved lancet tip at the distal end and a hub at the proximal end for guidewire access. The nitinol tube / needle can move at limited displacement inside the shaft by moving a sliding knob in the catheter handle. The nitinol tube (with the PTFE sleeve) and the polyimide shaft may rotate together using a rotation knob on the catheter handle.

Comparison of Technological Characteristics:

The Upstream GoBack Crossing Catheter is identical to the predicate Upstream GoBack Crossing Catheter in its basic design, intended use, Indications for Use statement, mechanism of action, operating principle, and sterilization method. The principal changes to the subject device relative to the predicate are limited to: (i) the availability of the subject device in two diameters (0.96 mm (2.9 Fr) or 1.4 mm (4 Fr)) and two lengths (80 cm and 120 cm); (ii) a PTFE sleeve with Pebax outer surface covering the distal tip inner metal surface; and (iii) non-coring treatment of the needle heel. Additionally, the 4 Fr model stainless steel distal tip is partially covered by Nylon 12 and the 2.9 Fr model has a proportionally smaller shaft, PTFE sleeve, distal tip, RO marker, needle diameter, spine height and needle protrusion (7 mm vs. 11 mm) than the than the 4 Fr subject device model and 4 Fr predicate device (which are identical across these characteristics) .

The predicate and all models of the Upstream GoBack Crossing Catheter are comprised of biocompatible materials and are single-lumen, single-use, devices that incorporate a distal curved lancet tip of a slid able nitinol tube, a SS304 metal tube section to hold the curved needle inside the catheter tip, and a proximal handle with female luer hub. The predicate and all models of the Upstream GoBack Crossing Catheter have a mechanism for device navigation and function through the peripheral vasculature. Warnings against use of polymer coated guidewires or use in re-entry applications were removed from the subject Upstream GoBack Crossing Catheter labeling. Removal of these warnings was validated in bench and clinical testing. Furthermore, design verification and validation testing conducted with the GoBack Crossing Catheter demonstrates that the device continues to meet all previous performance specifications and that minor differences in technological features do not impact the safety or effectiveness of the subject device.

Performance Testing Summary:

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

BIOCOMPATIBILITY TESTING

Biocompatibility testing was performed on subject devices containing Nylon 12 and Pebax in compliance with U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR Part 58 and per ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, as well as applicable FDA biocompatibility guidance including:

- Cytotoxicity
- Sensitization
- Irritation/intracutaneous reactivity
- Systemic toxicity (acute)
- Hemocompatibility (hemolysis, complement activation and thromboresistance)
- LAL and Material Mediated pyrogenicity

DEVICE DIMENSIONAL AND FUNCTIONAL TESTING

Performed on sterile 2.9 Fr and 4 Fr models:

- Particulates testing
- Torque testing (torque at break and transfer torque forces)
- Force at break testing
- Delivery testing
- Radio-opacity testing
- Surface testing
- Needle tip protrusion testing
- Catheter dimensions testing

Performed on a sterile 2.9 Fr model:

- Air leakage testing
- Liquid leakage testing
- Force at break testing
- Radio-opaque
- RO marker movement
- Bend to kink testing
- Needle penetration testing
- Transfer torsional forces

OTHER PERFORMANCE TESTING

- Testing was performed in which polymer coated guidewires from different manufacturers were passed through the GoBack Crossing Catheter models to demonstrate that no coating abrasion or peeling occurs with the non-coring needle tip
- A 2 year shelf life was established for the subject device

CLINICAL TESTING

Retrospective data from 151 patients demonstrated that the GoBack Crossing Catheter performed equivalently to the predicate in subintimal re-entry procedures. The clinical study demonstrates that the modified GoBack Catheter can be used for both intraluminal lesion crossing and for subintimal reentry. The GoBack Catheter device was used for intraluminal crossing in 62 subjects with a technical success rate of 88.7%, and for subintimal re-entry crossing in 89 subjects with a similar technical success rate of 88.8%. Across all procedures the major adverse event (MAE) rate was 0%.

Conclusions:

The Upstream GoBack Crossing Catheter and the predicate device have the same intended use and indications, and very similar technological characteristics and principles of operation. The minor labeling updates and technological differences between the Upstream GoBack Crossing Catheter and its predicate do not raise different 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. Additional performance and clinical testing demonstrates that the Upstream GoBack Crossing Catheter has a safety and effectiveness profile that is substantially equivalent to the predicate. Thus, the modified Upstream GoBack Crossing Catheter is substantially equivalent to the predicate GoBack Crossing Catheter.