April 2, 2020

Nitiloop Ltd.
℅ Wanda Carpinella
VP Regulatory Affairs
Boston Biomedical Associates, LLC
One Crowley Drive, Suite 216
Marlborough, Massachusetts 01752

Re: K193322
Trade/Device Name: NovaCross CTO Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 3, 2020
Received: March 4, 2020

Dear Wanda Carpinella:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193322

Device Name
NovaCross CTO Microcatheter

Indications for Use *(Describe)*
The NovaCross CTO Microcatheter is intended to facilitate the intraluminal placement of conventional and steerable guidewires beyond the stenotic lesions, including chronic total occlusions (CTOs), and prior to PTCA or stent intervention. It is also intended to be used in conjunction with a steerable guidewire to access discrete regions of the coronary and peripheral vasculature and for guidewire exchange.

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.

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Traditional Premarket Notification Submission – 510(k)

NovaCross™ CTO Microcatheter

510(k) Number K193322

Date Prepared: April 1, 2020

I. SUBMITTER

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II. DEVICE

Name of Device: NovaCross™ CTO Microcatheter Common or
Usual Name: NovaCross™ CTO Microcatheter Classification
Name: Percutaneous catheter (21 CFR 870.1250) Regulatory
Class: II
Product Code: DQY

III. PREDICATE DEVICE

Nitiloop Ltd. believes that the NovaCross™ CTO microcatheter, which is the subject of this notification, is substantially equivalent to the following predicate device:

- Boston Scientific; BridgePoint Medical system cleared under K102725
- ASAHI® Cosair and Cosair Pro Microcatheter cleared under K171933

In addition, the following reference device is used:

- Nitiloop Ltd. NovaCross™ Microcatheter cleared under K143608 and K160389.

IV. DEVICE DESCRIPTION

The NovaCross™ CTO Microcatheter is a sterile, single-use, single lumen, over-the-wire, disposable percutaneous support catheter designed to facilitate the intraluminal placement of conventional and steerable guidewires beyond stenotic lesions (including chronic total occlusions) prior to PTCA or stent intervention and to be used in conjunction with a steerable guidewire to access discrete regions of the coronary and peripheral vasculature. The NovaCross™ CTO Microcatheter consists of stainless steel shaft, Over Tube, and a proximal Handle Body that allows for manual device manipulation and a means for flushing the catheter lumen. A key element of the device is a temporarily deployable and collapsible distal Nitinol Scaffold, which is visible through fluoroscopy when deployed by the user, and expands to the width of the artery to provide an anchoring to aid the user in establishing greater support near the treatment site.

Subsequent to conventional guidewire placement, therapeutic devices such as atherectomy devices, PTCA catheters, and/or stents may be used to provide therapeutic benefit. The NovaCross™ CTO Microcatheter by itself does not provide therapeutic benefit beyond simple facilitation of guidewire support. The NovaCross™ CTO Microcatheter is similar in its design and it achieves its intended use by means of the same mechanisms as the predicate devices.

V. INDICATIONS FOR USE

The NovaCross™ CTO Microcatheter device is intended to facilitate the intraluminal placement of conventional and steerable guidewires beyond stenotic lesions, including chronic total occlusions (CTO), prior to PTCA or stent intervention. It is also intended to be used in conjunction with a steerable guidewire to access discrete regions of the coronary and peripheral vasculature and for guidewire exchange.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE AND REFERENCE DEVICE

The NovaCross™ CTO and the BridgePoint medical system and the ASAHI® Cosair / Cosair Pro Microcatheter have the same intended use. The NovaCross™ CTO and the BridgePoint Medical (the CrossBoss element), are both manufactured with stainless steel shafts with a lumen which is compatible for 0.014 guidwires. Also, both have stabilization systems - the BridgePoint system has an inflated balloon (Stingray) and the NovaCross™ CTO uses a nitinol scaffold. The ASAHI Corsair / Corsair Pro Microcatheters are also composed of a stainless steel shaft that supports placement of the guidewire beyond the chronic total occlusion.

The reference device, the cleared NovaCross™ MicroCatheter, and the NovaCross™ CTO have the same operating principles. Both use a Nitinol element (the superelasticity of the Nitinol is used), as the material to provide support to the guidewire and both include the same delivery system although the NovaCross™ CTO includes minor design modifications compared to the NovaCross™ device.

Questions related to clinical performance have been evaluated for the NovaCross™ CTO Microcatheter through extensive design verification and validation testing, including an IDE Clinical Study.

VII. PERFORMANCE DATA

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

Biocompatibility testing

An evaluation of biocompatibility for the NovaCross™ CTO microcatheter was conducted in accordance with FDA guidance, Use of International Standard ISO 10993-1. Testing included cytotoxicity, sensitization, intracutaneous study, pyrogenicity, SC5b-9 complement activation assay and hemolysis. All materials and processes of the NovaCross™ CTO device were shown to be biocompatible.

Sterilization, Packaging and Shelf Life Testing

The NovaCross™ CTO Microcatheter will be sterilized by EO gas. The sterilization cycle has been validated in compliance with ISO 11135:2014. In addition, shelf life and packaging testing were performed to support the labeled shelf life. All tests were successfully completed.

Mechanical Testing

Mechanical bench testing that has been performed on the NovaCross™ Microcatheter included the following:

- Dimensional
- Simulated use
- Tip flexibility
- Torque response
- Tensile strength
- Fluid leak
- Air leakage into hub assembly during aspiration
- Pushability and retractability
- Scaffold durability

All tests met the predefined acceptance criteria and demonstrate substantial equivalence to the predicate NovaCross device and support a one year shelf life for the NovaCross™ Microcatheter.

Particulate and lubricity and corrosion testing were leveraged from the predicate NovaCross™ Microcatheter.

VIII. CLINICAL DATA

A multicenter, non-randomized, open label, single arm pivotal study was conducted to assess the safety and efficacy of the NovaCross™ CTO Microcatheter device in subjects undergoing Percutaneous Cardiac Intervention for Chronic Total Occlusion. The study was performed in two cohorts, and included 186 subjects that were recruited in 10 investigational sites.

Primary Safety Endpoint

The primary safety endpoint of the study was the rate of post-procedure MI rate, defined as > X3 upper normal limit of CK-MB cardiac biomarker. the overall MACE rate observed in the combined analysis of cohort A and cohort B was 12.3% for the ITT population, with an upper confidence interval of 19.41% (97.5% CI). The following tables summarize the MACE rate according to each definition and for the ITT population for both device- related and not related events.

MACE events composite for ITT population

Category	Statistics	Cohort A (N=145)	Cohort B (N=41)	Cohort A + B (N=186)	97.5% Upper CI[1]	P-Value [1]
MACE	% (n/N)	14.0% (16/114)	7.3% (3/41)	12.3% (19/155)	19.41%	0.0020
Death	N	0	0	0		
Protocol definition of MI	N	16	3	19		
Urgent revascularization	N	0	0	0		

MACE defined as the composite of death, protocol definition of MI (CK-MB>3X ULN), or urgent revascularization (target vessel revascularization (TVR) or urgent coronary artery bypass surgery (CABG)).

Primary Effectiveness Analysis

Primary effectiveness endpoint was set as a technical success, which was defined as the ability of the NovaCross™ CTO Microcatheter to successfully facilitate placement of a guidewire beyond a native coronary chronic total occlusion (CTO) in the true vessel lumen. The results of the study showed a technical success of 75.3%.

Summary of Primary Effectiveness Endpoint for ITT Population:

Category	Statistics	Cohort A (N=145)	Cohort B (N=41)	Cohort A + B (N=186)
Technical success	% (n/N)	75.9% (110/145)	73.2% (30/41)	75.3% (140/186)

The results of this pivotal study show that the device has met both the primary safety endpoint and the primary effectiveness endpoint. It also met the secondary endpoints, associated with both the effectiveness and safety of the device. It was therefore concluded that the device is safe, effective and easily used and handled by interventional cardiologists.

IX. CONCLUSIONS

The NovaCross™ CTO Microcatheter was determined to be substantially equivalent to the predicate device.