October 18, 2017

Nitiloop Ltd.
% Mr. Michael Daniel
President
Daniel & Daniel Consulting, LLC
340 Jones Lane
Gardnerville, Nevada 89460

Re: K172297
Trade/Device Name: NovaCross Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 14, 2017
Received: September 18, 2017

Dear Mr. Michael Daniel:

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 Industry and Consumer Education (DICE) 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 Industry and Consumer Education (DICE) 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,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K172297

Device Name
NovaCross™ Microcatheter

Indications for Use *(Describe)*
The NovaCross™ Microcatheter is 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.

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510(k) SUMMARY
NitiLoop NovaCross™ Microcatheter

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Date Prepared: July 25, 2017

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Device:

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

Predicate Device:

The predicate device is the NovaCross™ Microcatheter, cleared under K143608 and K160389.

Purpose of the Special 510(k) submission:

The NovaCross™ Microcatheter Special 510(k) was submitted to implement modifications to the NovaCross™ Microcatheter.

Intended Use:

The NovaCross™ Microcatheter is intended to be used in conjunction with a steerable guidewire to access discrete regions of the coronary and peripheral vasculature and for guidewire exchange.

Technological Characteristics:

The NovaCross™ Microcatheter is a sterile, single-use, single lumen, over-the-wire, disposable percutaneous support catheter designed for use in conjunction with a steerable guidewire to access discrete regions of the coronary and peripheral vasculature for guidewire exchange.

The NovaCross™ Microcatheter consists of telescopic shaft, over tube, and a proximal handle 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 retractable 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.

The NovaCross™ Microcatheter is similar in its design and it achieves its intended use by means of the same mechanisms as the predicate device. Minor modifications were implemented including the addition of a middle tube, a shorter handle, increasing the scaffold ID and OD, and increasing the device outer diameter.

Performance Data:

To evaluate the modifications to the NovaCross Microcatheter, the following tests were performed:

- Simulated use testing
- Biocompatibility testing – based upon a biological risk assessment, cytotoxicity testing and hemolysis testing

- Mechanical tests, including a bond strength test, visibility test, radial force test, and axial force test.
- GLP animal study test to assess the new scaffold and device characteristics

Substantial Equivalence:

The modified NovaCross™ Microcatheter has the same intended use and similar indications, principles of operation, and technological characteristics as the cleared NovaCross™ Microcatheter. The minor differences in the handle design and in the materials do not raise any new questions of safety or effectiveness. Performance data demonstrates that the modified NovaCross™ Microcatheter is similar to the cleared NovaCross™ Microcatheter. Thus, the modified NovaCross™ Microcatheter is substantially equivalent to its predicate device.