



Food and Drug Administration  
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March 11, 2016

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

Re: K160389

Trade/Device Name: Novacross Microcatheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: DQY  
Dated: February 10, 2016  
Received: February 11, 2016

Dear 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 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 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 yours,

**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

**Indications for Use Statement**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

**Indications for Use**

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
*See PRA Statement on last page*

510(k) Number *(if known)*  
**K160389**

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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*“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.”*

K160389

**Attachment 4**



**510(k) SUMMARY**  
**NitiLoop's NovaCross™ Microcatheter**

**Submitter:**

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**Date Prepared: February 3, 2016**

**Contact Person:**

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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.

**Purpose of the Special 510(k) notice:**

The NovaCross™ Microcatheter is a modification to 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 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.

**Performance Data:**

The following tests are the same as those submitted in the original submission:

- **Simulated use** -the test was performed at baseline (immediately following assembly, prior to sterilization), Time 0 (after sterilization and simulated transportation), and Time 1 (after accelerated aging of 1 year and simulated transportation).
- **Tensile Strength**- The test was performed at baseline (immediately following assembly, prior to sterilization), Time 0 (after sterilization and simulated transportation), and Time 1 (after accelerated aging of 1 year and simulated transportation).

- **Kink resistance-** The test was performed at baseline (immediately following assembly, prior to sterilization), Time 0 (after sterilization and simulated transportation), and Time 1 (after accelerated aging of 1 year and simulated transportation).
- **Tip Flexibility-** the test was performed at baseline (immediately following assembly, prior to sterilization), Time 0 (after sterilization and simulated transportation), and Time 1 (after accelerated aging of 1 year and simulated transportation).

**Substantial Equivalence:**

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