July 20, 2021

Natec Medical Ltd.
% Candace Cederman
Principal Consultant
CardioMed Device Consultants LLC
1783 Forest Drive, Suite 254
Annapolis, Maryland 21401

Re: K210012
Trade/Device Name: Tamarin Blue PTCA RX Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX

Dear Candace Cederman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 9, 2021. Specifically, FDA is updating this SE Letter typo in the Company name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, 301-796-6075, Gregory.Oconnell@fda.hhs.gov.

Sincerely,

For Sara M. Royce -S
Digitally signed by Sara M. Royce -S
Date: 2021.07.20 17:55:34 -04'00'

Gregory O'Connell
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

July 9, 2021

Nantec Medical Ltd.
c/o Candace Cederman
Principal Consultant
CardioMed Device Consultants LLC
1783 Forest Drive, Suite 254
Annapolis, Maryland 21401

Re: K210012
Trade/Device Name: Tamarin Blue PTCA RX Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: June 9, 2021
Received: June 10, 2021

Dear Candace Cederman:

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,

Sara M. Royce -S
Digitally signed by Sara M. Royce -S
Date: 2021.07.09 16:46:28 -04'00'

For

Gregory O'Connell
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)*
K210012

Device Name
Tamarin Blue PTCA RX Dilatation Catheter

Indications for Use *(Describe)*
The Tamarin Blue PTCA RX Dilatation Catheters are indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion.

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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

"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."

510(k) Summary
[as required by 21 CFR 807.92(c)]

Tamarin Blue PTCA RX Dilatation Catheter
510(k) K210012

DATE PREPARED:	July 9, 2021
APPLICANT:	Natec Medical Ltd. Maeva Centre Building – Ebene Business Park Reduit 72201, Mauritius
CONTACT:	Roy Devassy Pallippatt, Regulatory Affairs Manager
TRADE NAME:	Tamarin Blue PTCA RX Dilatation Catheter
COMMON NAME:	PTCA RX Catheter
CLASSIFICATION REGULATION:	Catheters, transluminal coronary angioplasty, percutaneous (21 CFR §870.5100, Product Code LOX)
DEVICE CLASS:	Class II
PANEL CODE:	Cardiovascular
PREDICATE DEVICE:	Tamarin Blue PTCA RX Dilatation Catheter, K112735
REFERENCE DEVICES:	Filao NC RX PTCA Dilatation Catheter, K141933

INTENDED USE/INDICATIONS FOR USE:

The Tamarin Blue PTCA RX Dilatation Catheters are indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion.

DEVICE DESCRIPTION:

The Tamarin Blue PTCA RX Dilatation Catheter is a standard Rapid Exchange (RX) PTCA catheter with a single lumen proximally, a dual lumen distally, a semi-compliant inflatable balloon and a soft, tapered distal tip to aid in crossing tight stenoses. One lumen of the catheter's dual lumen is used for inflation and deflation of the balloon, and the other lumen allows guide wire access through the distal part of the catheter. The maximum recommended guide wire diameter is 0.014". A luer lock fitting (hub) allows connection with an inflation device. Two radiopaque markers on the guide wire lumen tubing provide visual reference points for balloon positioning across the stenosis. A hydrophilic coating has been applied on the distal portion of catheter i.e., up to the RX port, to improve catheter pushability. The balloon material expands to a known diameter at a specific pressure as defined in the compliance table supplied with the catheter.

The device is supplied sterile and intended for one-time use.

COMPARISON WITH PREDICATE DEVICE:

Comparisons of the Tamarin Blue PTCA RX Dilatation Catheter and the predicate device shows that the technological characteristics of the subject device such as components, design, sterilization method, shelf life and operating principle are identical to the currently marketed predicate device. Comparison of the subject device to the reference device show that the material, specifically the hydrophilic coating, are identical. Therefore, the addition of a hydrophilic coating to the subject device does not raise any new questions of safety or effectiveness.

The intended use/indications for use between the subject device and the predicate device are identical.

COMPARISON WITH PREDICATE AND REFERENCE DEVICES:

	Subject	Predicate	Reference
Device Name	Tamarin Blue PTCA RX Dilatation Catheter	Tamarin Blue PTCA RX Dilatation Catheter	Filao NC RX PTCA Dilatation Catheter
Manufacturer	Natec Medical Ltd	Natec Medical Ltd	Natec Medical Ltd
510(k)	-	K112735	K141933
Intended Use/Indication for Use	• balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion	• balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion	• balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion • balloon dilatation of a stent after implantation (balloon models 2.00mm – 4.50mm)
Regulation	21 CFR 870.5100	21 CFR 870.5100	21 CFR 870.5100
Regulation Name	Catheters, transluminal coronary angioplasty, percutaneous	Catheters, transluminal coronary angioplasty, percutaneous	Catheters, transluminal coronary angioplasty, percutaneous
Regulation Class	Class II	Class II	Class II
Product Code	LOX	LOX	LOX
Prescription/OTC	Prescription	Prescription	Prescription
Device Design/Processing			
Catheter Design	Rapid Exchange	Rapid Exchange	Rapid Exchange
Balloon diameter (mm)	1.5 - 4.0	1.5 - 4.0	2.0 - 4.5
Balloon length (mm)	8 to 30	8 to 30	8 to 30
Effective Length (mm)	1400	1400	1400
Balloon Compliance	Semi-compliant	Semi-compliant	Non-compliant
Coating	Hydrophilic	None	Hydrophilic
Sterilization Method	EO	EO	EO
Performance Specifications			
Nominal Pressure	8 atm	8 atm	12 atm
Rated Burst Pressure	16 atm	16 atm	20 atm

NON-CLINICAL TESTING/PERFORMANCE DATA:

Non-clinical bench testing was performed on the subject device to determine substantial equivalence. The testing performed is as follows:

- Coating Inspection
- Coating Integrity (Performance and Durability)
- Balloon preparation, deployment and retraction
- Balloon Rated Burst
- Balloon Fatigue
- Balloon compliance
- Balloon inflation/deflation
- Particulate

In vitro bench testing demonstrated that the hydrophilic coating performed as intended and did not impact the functionality of the device.

BIOCOMPATIBILITY:

The Tamarin Blue PTCA RX Dilatation Catheter was compared to the predicate and reference devices. Based on similarities of the materials used in the subject device to its predicates / reference devices, the biocompatibility of the Tamarin Blue PTCA RX Dilatation Catheter was verified to be the same as those of the predicates / reference devices.

The results are being leveraged due to the similarities in the underlying materials to which the hydrophilic coating is applied.

The results of the testing show that the subject device included in this submission met all acceptance criteria and the subject device is biocompatible.

CONCLUSION:

The Tamarin Blue PTCA RX Dilatation Catheter included in this notification is identical to the previously cleared predicate device in terms of intended use and technological characteristics. Any differences that exist between the Tamarin Blue PTCA RX Dilatation Catheter and the predicate did not raise any new questions of safety or effectiveness.

The Tamarin Blue PTCA RX Dilatation Catheter is substantially equivalent to the reference product cleared in the US in terms of biocompatibility.