DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 4, 2015

Natec Medical Ltd.
Mr. Xavier de Buchere
Regulatory Affairs & Quality Manager
Maeva Centre Building – Silicon Avenue
Ebene Business Park
Reduit, Mauritius 72201

Re: K143041
Trade/Device Name: Ebony PTA 0.014" OTW Catheter
Ebony PTA 0.018" OTW Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: May 7, 2015
Received: May 8, 2015

Dear Mr. de Buchere:

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

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 below.

510(k) Number *(if known)*
K143041

Device Name
Ebony® PTA 0.014" Over the Wire Catheter
Ebony® PTA 0.018" Over the Wire Catheter

Indications for Use *(Describe)*
The Ebony® PTA 0.014" over the wire Catheter is intended for dilatation of lesions in the femoral, popliteal and infrapopliteal arteries. The Ebony® PTA 0.014" over the wire Catheter is contraindicated for use in coronary arteries or neuro-vasculature.

The Ebony® PTA 0.018" over the wire Catheter is intended for dilatation of lesions in the femoral, iliac, popliteal, infrapopliteal and renal arteries. The Ebony® PTA 0.018" over the wire Catheter is not for use in coronary arteries or neuro-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

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

Applicant: Natec Medical Ltd.
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Official Correspondent: Xavier De Buchere
Regulatory Affairs & Quality Manager
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Summary Preparation Date: October 10th, 2014

Device Name:

Trade Name:	Ebony® PTA 0.014" over the wire Catheter Ebony® PTA 0.018" over the wire Catheter
Common/Usual Name:	Percutaneous Catheter 21 CFR 870.1250
Classification Name:	Catheters, Transluminal coronary angioplasty, Percutaneous
Generic name:	PTA Catheter
Regulation Number:	870.1250
Product Code:	LIT
Device Class:	Class II

Predicate Devices:

- Ebony® PTA .014" RX Peripheral Dilatation Catheter (K112513)
- Ebony® PTA 0.035 Peripheral Dilatation Catheter (K103354)

DEVICE DESCRIPTION

The Ebony ® PTA 0.014" over the wire catheter is a standard catheter with a balloon near the distal tip and a Y-connector at the proximal end. The guide wire lumen (inner tubing) permits the use of guide wires to facilitate advancement of the catheter to and through the stenosis to be dilated. Maximum guide wire diameter is 0.014” (0.36 mm). The usable catheter length for OTW is 120 cm and 150 cm.

In order to correctly position the balloon under fluoroscopy, two radiopaque markers are placed on the shaft under the balloon itself, defining its cylindrical area. The catheter includes a smooth, soft and atraumatic tip to facilitate advancement of the catheter through the stenosis. In order to facilitate advancing through the vasculature, a hydrophilic coating is present on the distal shaft and the balloon.

The Ebony ® PTA 0.014" over the wire catheter is available in 2 usable lengths: 120 and 150 cm; and in the balloon sizes shown in Table 1. The Ebony ® PTA 0.014" over the wire catheter will be supplied sterile and is intended for one time use.

			Catheter Length 120 cm and 150 cm					
Balloon			Balloon Length (mm)					
Size (mm)	20	40	60	80	100	120	150	200
1.50	✓							
2.00		✓	✓	✓	✓	✓	✓	✓
2.50		✓	✓	✓	✓	✓	✓	✓
3.00		✓	✓	✓	✓	✓	✓	✓
3.50		✓	✓	✓	✓	✓	✓	✓
4.00		✓	✓	✓	✓	✓	✓	✓

Table 1

The Ebony® PTA 0.018" over the wire Catheter is a standard catheter with a balloon near the distal tip and a Y-connector at the proximal end. The guide wire lumen (inner tubing) permits the use of guide wires to facilitate advancement of the catheter to and through the stenosis to be dilated and it ends at the tip of the catheter. Maximum guide wire diameter is 0.018” (0.46 mm).

The balloon has radiopaque marker(s) to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter and length at a specific pressure.

The Ebony® PTA 0.018” over the wire Catheter is available in two catheter lengths and the balloon sizes shown in Table 2 below. The Ebony® PTA 0.018” over the wire Catheter is supplied sterile and is intended for one time use.

Balloon		Balloon Length (mm)					
Size (mm)	40	60	80	100	120	150	200
2.00	✓	✓	✓	✓	✓	✓	✓
2.50	✓	✓	✓	✓	✓	✓	✓
3.00	✓	✓	✓	✓	✓	✓	✓
3.50	✓	✓	✓	✓	✓	✓	✓
4.00	✓	✓	✓	✓	✓	✓	✓
5.00	✓	✓	✓	✓	✓	✓	✓
5.50	✓	✓	✓	✓	✓	✓	✓
6.00	✓	✓	✓	✓	✓	✓	✓
7.00	✓						

Table 2

DEVICE INTENDED USE

The Ebony 0.014" PTA over the wire Catheter is intended for dilation of lesions in the femoral, popliteal and infrapopliteal arteries. The Ebony 0.014" PTA over the wire Catheter is contraindicated for use in coronary arteries or neuro-vasculature.

The Ebony PTA .018" over the wire Catheter is intended for dilation of lesions in the femoral, iliac, popliteal, infrapopliteal and renal arteries. The Ebony PTA .018" OTW over the wire Catheter is not for use in coronary arteries or neuro-vasculature.

COMPARISON OF INDICATIONS FOR USE TO PREDICATE DEVICES & TECHNICAL CHARACTERISTICS

The modified Ebony® PTA 0.014" OTW Catheter is manufactured using the same materials that were used to manufacture the predicate Ebony® PTA 0.014" RX Peripheral Dilatation Catheter and the predicate Ebony PTA 0.035" Peripheral Dilatation Catheter.

The modified Ebony® PTA 0.014" OTW Catheter differs from the originally cleared Ebony® PTA 0.014" RX Peripheral Dilatation Catheter with respect to the intended use, device design, and the available balloon sizes and catheter lengths. The intended use of the modified Ebony catheter in the femoral, popliteal and infra popliteal arteries, is a more restricted indication from the originally cleared indication. As this is a subset of the original indication, safety and effectiveness would not be affected.

The OTW and proximal connector design changes of the modified Ebony PTA 0.014" OTW Catheter are similar in design to the predicate Ebony PTA 0.035" Peripheral Dilatation Catheter. The available balloon sizes are an extension of the sizes for the predicate Ebony® PTA 0.035" Peripheral Dilatation Catheter.

The performance of the modified catheter design and new balloon sizes is supported by the bench test results which found that all catheter test samples met the acceptance criteria for each of the performance tests.

The modified Ebony® PTA 0.018" OTW Catheter has the same indication and uses the same materials that were used to manufacture the predicate Ebony PTA 0.035" Peripheral Dilatation Catheter and the predicate Ebony® PTA 0.014" RX Peripheral Dilatation Catheter.

The modified Ebony® PTA 0.018" OTW Catheter differs from the originally cleared Ebony® PTA 0.035" Peripheral Dilatation Catheter with respect to the device design, available balloon sizes and catheter lengths. To accommodate 0.018" guidewires, the design of the modified Ebony® PTA 0.018" OTW Catheter has a smaller inner tubing than the predicate Ebony® PTA 0.035" Peripheral Dilatation Catheter.

The available balloon sizes are expanded with the addition of balloon diameters 1.5mm and 2.0 to 5.0 mm diameter balloons. The rated burst pressure and catheter length are the same or fall within the range of the predicate Ebony® PTA 0.035" Peripheral Dilatation Catheter, and balloon lengths are expanded.

The performance of the modified catheter design and new balloon sizes is supported by the bench test results which found that all catheter test samples met the acceptance criteria for each of the performance tests.

BIOCOMPATIBILITY

All materials used in the Ebony ® PTA 0.014" over the wire catheter and Ebony® PTA 0.018" over the wire catheter are biocompatible based on the results of biocompatibility testing performed in accordance with ISO10993 Part 1, 2, 4, 5, 10, 11, 12, ASTM F75600 and 21 CFR 58 (GLP regulations).

PERFORMANCE DATA

The substantial equivalence of the Ebony ® PTA 0.014" over the wire catheter and Ebony® PTA 0.018" over the wire catheter has been demonstrated through data collected from in vitro bench tests and analyses. Testing results demonstrated equivalent performance of the Ebony® PTA 0.014" over the wire catheter and the Ebony® PTA 0.018" over the wire catheter with the predicate device.
The testing included

- balloon compliance
- balloon burst pressure
- balloon fatigue
- shaft resistance
- bond strength
- catheter dimensions
- deflation time
- coating verification
- kink testing
- deployment testing
- guide wire and introducer compatibility.

CONCLUSION

The subject devices, the Ebony ® PTA 0.014" over the wire catheter and the Ebony® PTA 0.018" over the wire catheter, met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. Natec Medical believes the Ebony ® PTA 0.014" over the wire catheter and Ebony® PTA 0.018" over the wire catheter are substantially equivalent to the predicate devices.