June 29, 2022

Natec Medical Ltd.
Roy Devassy Pallippatt
Regulatory Affairs & Quality Manager
Maeva Centre Building, Silicon Avenue, Ebene Business Park
Reduit, 72201
Mauritius

Re: K220410
Trade/Device Name: Ebony HP PTA OTW 0.035" Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT
Dated: May 20, 2022
Received: May 26, 2022

Dear Roy Devassy Pallippatt:

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,

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)*
K220410

Device Name
Ebony HP PTA OTW 0.035" Catheter

Indications for Use *(Describe)*
The Ebony HP PTA OTW 0.035" Catheter is indicated for;
• Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
• Post-dilatation of balloon expandable and self-expanding stents in the peripheral 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.

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Preparation Date: June 28, 2022

Device Name:

Trade Name:	Ebony HP PTA OTW 0.035" Catheter
Common/Regulatory name:	Percutaneous catheter
Classification Name:	Percutaneous transluminal angioplasty catheter
Generic name:	PTA Catheter
Regulation Number:	21 CFR 870.1250
Product Code:	LIT
Device Class:	Class II

Predicate Device: ▪ Charger PTA Balloon Dilatation Catheter - K112697
Reference Device: ▪ Ebony PTA 0.035 Peripheral Dilatation Catheter - K143036/K103354

Device Description:

The Ebony HP PTA OTW 0.035" Catheter is a standard Over The Wire (OTW) PTA catheter with a non-compliant inflatable balloon at the distal part with an atraumatic, tapered tip at its distal end to facilitate advancement of the catheter through the stenosis, and a luer lock fitting (Y hub) at the proximal end allowing the connection with an inflation device.

The catheter is a two lumen catheter; one lumen is used for inflation / deflation of the balloon and accessed via the lateral port of the Y hub. The second lumen, starting at the straight entry port of the Y hub, allows access to the distal tip of the catheter for guide wire insertion. The maximum recommended guide wire diameter is 0.035". The internal tubing of the balloon has two radio opaque markers to provide visual reference points for balloon positioning relative to the stenosis within the vessel. The working pressure range for the balloon is between the nominal pressure (NP) and the rated burst pressure (RBP).

A hydrophilic coating solution is applied on the distal section of the shaft and on the balloon to improve the pushability of the catheter by reduction of the friction coefficient of the outer body.

The Ebony HP PTA OTW 0.035" catheter is available in following sizes;

Table 1: Balloon Size Matrix

Catheter Usable lengths 40, 75 & 135 cm									
Balloon Size		Balloon Length (mm)							
		20	40	60	80	100	120	150	200
Balloon Diameter (mm)	3.00	✓	✓	✓	✓	✓	✓	✓	✓
	4.00	✓	✓	✓	✓	✓	✓	✓	✓
	5.00	✓	✓	✓	✓	✓	✓	✓	✓
	6.00	✓	✓	✓	✓	✓	✓	✓	✓
	7.00	✓	✓	✓	✓	✓	✓	✓	✓
	8.00	✓	✓	✓	✓	✓	✓	✓	✓
	9.00	✓	✓	✓	✓				
	10.00	✓	✓	✓	✓				
	12.00	✓	✓	✓	✓				

Note: For Catheters with usable length 75 & 135 cm all the sizes are available.
Catheter with usable length 40 cm is available only in balloon length up to 100mm for all available balloon diameter and only for balloon diameter 5.00 & 6.00 it is available in balloon length up to 120mm.

Device Indication for Use:

The Ebony HP PTA OTW 0.035" Catheter is indicated for:

- Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
- Post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

Comparison of Technical Characteristics:

The design, materials and manufacturing of the Ebony HP PTA OTW 0.035" Catheter is same or similar to those used for the predicate devices. The intended use for the Ebony HP PTA OTW 0.035" Catheter is also comparable to the predicate devices.

Biocompatibility:

All materials used in the Ebony HP PTA OTW 0.035" Catheter are biocompatible based on biocompatibility testing results. The device has been tested according to "ISO 10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" and 21 CFR 58 (GLP regulations).

The following biocompatibility tests were completed on the Ebony HP PTA OTW 0.035" Catheter;

- Acute Systemic Toxicity Study
- Cytotoxicity Study
- Hemocompatibility Study
- Hemolysis Test
- Partial Thromboplastin Time (PTT)
- Sc5b-9 Complement Activation
- Intracutaneous Reactivity Test
- Material Mediated Pyrogen Test
- Skin Sensitization Study
- Thrombogenicity in Canine Study

Performance Data:

Substantial equivalence has been demonstrated based on the results of non-clinical testing on the Ebony HP PTA OTW 0.035" Catheter which addressed the following considerations:

- Dimensional Verification
- Balloon Fatigue test (Repeat Balloon Inflations)
- Catheter Torque Strength evaluation
- Balloon Fatigue in stent (Repeat Balloon Inflations)
- Balloon Inflation and Deflation Time
- Balloon Rated Burst Pressure (RBP) and compliance test
- Balloon Rated Burst Pressure (RBP in Stent)
- Catheter Bond (sleeve, hub and tip) Strength
- Balloon Preparation, Deployment and Retraction
- Coating Inspection
- PTA Catheter Performance test
- Sizing & counting of particulate matter on catheters (Particulate evaluation)

Conclusion:

The subject device, the Ebony HP PTA OTW 0.035" Catheter met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, FDA guidance documents and test protocols. No new questions of safety or effectiveness were raised during the testing program.

Based on the similarities in the indication for use, device design, materials and the results of the non-clinical testing and analysis, the Ebony HP PTA OTW 0.035" Catheter is considered substantially equivalent to the aforementioned predicate devices.