DEC - 9 2011

510(k) SUMMARY

807.92(c)

SPONSOR

807.92(a)(1)

Company Name:	Natec Medical Ltd.
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Contact Person:	Alain Valorge Quality Manager info@natec-medical.com

Summary Preparation Date: July 14, 2011

DEVICE NAME

807.92(a)(2)

Trade Name:	Ebony® PTA .014" RX Peripheral Dilatation Catheter
Common/Usual Name:	PTA .014" Catheter
Classification Name:	Percutaneous Catheter
Regulation Number:	21 CFR 870.1250
Product Code:	LIT and DQY
Device Class:	Class II

PREDICATE DEVICE

807.92(a)(3)

Legally Marketed Equivalent Devices:

- Invatec Amphirion Deep PTA 0.014'' Balloon Catheter - K083919
- Cordis AVIATOR Plus PTA Balloon dilatation catheter - K071189
- Boston Ultra Soft SV PTA Dilatation Catheter – K050389

DEVICE DESCRIPTION

807.92(a)(4)

The Ebony® PTA 0.014" Peripheral Dilatation Catheter is a standard Rapid Exchange (RX) PTA catheter with a semi-compliant inflatable balloon at the distal part and an atraumatic, tapered tip to aid in crossing the tight stenoses.

The catheter is double lumen in the distal part, one lumen is used for inflation and deflation of the balloon, and the second lumen allows access to the distal part of the catheter for guide wire insertion (max. 0.014"). The maximum recommended guide wire diameter is 0.014". A luer lock fitting (Hub) allows the connection with an inflation device. 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.

An hydrophilic coating solution is applied on the catheter body to improve the pushability of the catheter by reduction of the friction coefficient of the outer body. The balloon material expands to a known diameter at specific pressure defined in a compliance table supplied with the catheter. The device is available in balloon diameter of 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 7.0, 8.0 mm, and balloon lengths of 10, 15, 20, 25, 30, 35, 40, and 60 mm.
It will be supplied sterile and is intended for one time use.

DEVICE INTENDED USE 807.92(a)(5)

The Ebony 0.014" PTA Catheter is intended for dilatation of lesions in the iliac, femoral, popliteal, infra popliteal, renal and carotid arteries.
This catheter is not for use in coronary or neuro-vasculature.

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

The Ebony® PTA .014" Dilatation Catheter incorporates substantially equivalent indications for use, design, and dimensional and performance specifications as those found with the aforementioned predicate devices.

NONCLINICAL TESTS 807.92(b)

SAFETY and EFFECTIVENESS

BIOCOMPATIBILITY

All materials used in the Ebony® PTA .014" Catheter are biocompatible based on biocompatibility testing results. The device has been tested according to ISO 10993 Part 1, 2, 4, 5, 10, 11, 12, ASTM F756-00 and 21 CFR 58 (GLP regulations)

PERFORMANCE DATA

The safety and effectiveness of the Ebony® PTA .014" Catheter has been demonstrated via data collected from non-clinical tests and analyses, which addressed, among other considerations, the following:

- Biocompatibility
- Balloon compliance
- Balloon burst pressure
- Balloon fatigue (repeated balloon inflation) endurance
- Balloon inflation/deflation performance
- Bond strengths
- Catheter dimensions and balloon profile
- Catheter body minimum burst strength
- Device preparation (guide wire and introducer compatibility)

CONCLUSION

807.92(b)(3)

The subject device, the Ebony® PTA 0.014" Catheter, met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, and test protocols.

Since the Ebony® PTA 0.014" Catheter have the same intended use, similar design and technological characteristics, equivalent performance properties, identical sterilization and packaging, same mode of operation, and no new safety or effectiveness issues, the Ebony® PTA 0.014" Catheter may be considered substantially equivalent to the aforementioned predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DEC - 9 2011

NATEC Medical Ltd.
c/o E.J. Smith
Smith Associates
1468 Harwell Ave.
Crofton, MD 21114

Re: K112513
Trade/Device Name: Ebony PTA 0.014" Peripheral Dilatation Catheter
Regulation Number: 21 CFR 870. 1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: LIT, DQY
Dated: November 23, 2011
Received: November 23, 2011

Dear Mr. Smith:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

M. A. Hillebrenner

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

510(k) Number: K112513

Device Name: Ebony 0.014 PTA Catheter

Indication for Use: The Ebony 0.014'' PTA Catheter is intended for dilatation of lesions in the iliac, femoral, popliteal, infra popliteal, renal and carotid arteries.
This catheter is not for use in coronary or neuro-vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The –Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M.A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular De

510(k) Number K112513