510(k) Summary

807.92(c)

FEB 2 3 2011

SPONSOR **807.92(a)(1)**

Company Name:	Natec Medical Ltd.
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Summary Preparation Date: October 28, 2010

DEVICE NAME **807.92(a)(2)**

Trade Name:	Ebony® PTA .035 Peripheral Dilatation Catheter
Common/Usual Name:	PTA Catheter
Classification Name:	Percutaneous Catheter
Regulation Number:	21 CFR 870.1250
Product Code:	LIT
Device Class:	Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

K Number	Trade Name	Manufacturer
K062809	ADMIRAL XTREME™ PTA Catheter	Invatec Innovative Technologies

DEVICE DESCRIPTION **807.92(a)(4)**

The Ebony® PTA .035 Peripheral Dilatation Catheter is a standard Over the Wire (OTW) PTA Catheter with a semi-compliant inflatable balloon at the distal part and an atraumatic, tapered tip to aid in crossing tight stenoses.

It is a double lumen catheter, one lumen for the guide wire used for inflation/deflation of the balloon and one lumen for the guide wire used to access to the distal tip of the catheter (max/0.035"). A luer lock fitting allows the connection with an inflation device (Y hub). The balloon has two radiopaque markers to provide visual reference points for balloon positioning relative to the stenosis within the vessel.

The distal catheter, proximal to the balloon, is covered with a hydrophilic coating to improve the trackability and pushability characteristics.

The balloon material expands to a known diameter at specific pressure defined in a compliance chart supplied with the catheter. The device is available in balloon diameters of 5, 6, 7, 8, 9, 10 or 12 mm, balloon lengths of 20, 40, 60, or 80 mm and catheter lengths of 80, 130, or 150 cm.
It will be supplied sterile and is intended for one time use.

DEVICE INTENDED USE **807.92(a)(5)**

The Ebony® .035 PTA Catheter is intended for the dilation of lesions in the femoral, iliac, popliteal, infrapopliteal and renal arteries.

The Ebony® .035 PTA Catheter is not for use in coronary arteries or neuro-vasculature.

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

The Ebony® .035 PTA Catheter and the predicate device, Admiral Xtreme™ PTA Catheter have the same intended use for the dilatation of lesion in the femoral, iliac, infra popliteal and renal arteries. The technological characteristics such as material, biocompatibility, mode of operation, performance properties, sterilization and packaging are substantially equivalent to the predicate device.

NONCLINICAL TESTS **807.92(b)**

SAFETY and EFFECTIVENESS

BIOCOMPATIBILITY

All materials used in the Ebony® .035 PTA 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® .035 PTA Catheter has been demonstrated through data collected from in vitro bench tests and analyses. Testing results demonstrated equivalent performance of the Ebony® .035 PTA Catheter with the predicate device.
The testing included balloon compliance, balloon burst pressure, balloon fatigue, shaft resistance, bond strength, catheter dimensions, deflation time and guide wire and introducer compatibility.

CONCLUSION **807.92(b)(3)**

The subject device, the Ebony® .035 PTA Catheter, met all the predetermined acceptance criteria of design verification and validation as specified by applicable

standards, guidance, and test protocols. It is the conclusion of Natec Medical, Ltd that the Ebony® .035 PTA Catheter is as safe and effective as the predicate device.

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

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

FEB 2 3 2011

Re: K103354
Trade/Device Name: Ebony .035 PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name:
Regulatory Class: Class II (two)
Product Code: LIT
Dated: February 8, 2011
Received: February 9, 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.

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 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K103354

Device Name: Ebony .035 PTA Catheter

Indications for Use:

The Ebony® .035 PTA Catheter is intended for the dilation of lesions in the femoral, iliac, popliteal, infrapopliteal and renal arteries.

The Ebony® .035 PTA Catheter is not for use in coronary arteries or neuro-vasculature.

Prescription Use _____ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103354