K112634 page 1/2

Inotec AMD Ltd

510(k) Summary of Safety and Effectiveness

JUL 3 2012

Manufacturer and Submitter

Company Name:	Inotec AMD Ltd.
Company Address:	Unit 4a Butts Business Centre, Fowlmere, Cambridge Cambridgeshire SG8 7TS, UK Tel 44(0) 1763 207222
Contact Person:	Nicholas Hyde
Date Summary Prepared:	April 16, 2012

Device

Trade/Device Name:	NATROX™ Topical Oxygen Delivery System with Accessories
Common/Usual Name:	Topical Oxygen Chamber
Classification Name:	Chamber, Oxygen, Topical, Extremity
Regulation Number:	21 CFR 878.5650
Product Code:	KPJ
Classification Panel:	General & Plastic Surgery
Classification:	Class II

Substantial Equivalence

This 510(k) submission demonstrates that the NATROX™ Topical Oxygen Delivery System is substantially equivalent to the Oxybox System (Oxyfast Corporation, K023456) and the TransCu O2 (Electrochemical Oxygen Concepts, Inc., K090681), which are similar in both technology and intended use to the subject device.

Device Description

The NATROX™ Topical Oxygen Delivery System is a small battery-powered electronic device approximately the size of a cell phone, containing an oxygen generator that produces 99% oxygen from room air at a rate of approximately 13 mL/hour. A small diameter tube transmits the oxygen to the wound bed, where the wound is exposed to the oxygen atmosphere inside the Oxygen Delivery System (ODS), Island Oxygen Delivery Pad (IODP) wound dressing or into the patient's own wound dressing. The NATROX™ System provides oxygen to diffuse evenly over the wound bed under an occlusive dressing, constantly refreshing the oxygen supply to enhance the normal process of wound healing for chronic and hard-to-heal wounds with compromised oxygen delivery to healing tissue.

Intended Use/Indications for Use

The NATROX™ System is a low-dose tissue oxygenation system intended to provide topical oxygen to aid in the healing of chronic wounds such as:

- Skin ulcerations due to diabetes, venous stasis, post surgical infections and gangrenous lesions,
- Decubitis ulcers (bedsores),
- Amputations/infected stumps,
- Skin grafts,
- Burns, and
- Frostbite

Performance - Bench Testing

The NATROX™ Topical Oxygen Delivery System has been tested according to IEC 60601-1, IEC 60601-1-2 and was found to meet all requirements. Performance data also support that the NATROX™ device and accessories meet the specified criteria.

Performance - Clinical Evaluation

A clinical study in 10 patients was conducted using to support the safety, efficacy and usability of the VELOX device, which is an earlier version of the NATROX™ that produces the same oxygen concentration and oxygen flow. This 6-week study demonstrated that use of the VELOX device significantly reduced wound size and wound pain, did not result in adverse effects, and supported the usability of the 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

JUL 3 2012

Inotec AMD Limited
% Mandell Horwitz Consultants, LLC
Ms. Diane Horwitz
2995 Steven Martin Drive
Fairfax, Virginia 22031

Re: K112634
Trade/Device Name: NATROX™ Topical Oxygen Delivery System with Accesories
Regulation Number: 21 CFR 878.5650
Regulation Name: Topical oxygen chamber for extremities
Regulatory Class: Class II
Product Code: KPJ
Dated: June 15, 2012
Received: June 15, 2012

Dear Ms. Horwitz:

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.

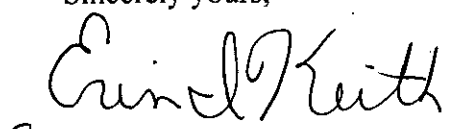
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112634

Device Name: NATROX™ Topical Oxygen Delivery System

Indications For Use:

The NATROX™ System is a low-dose tissue oxygenation system intended to provide topical oxygen to aid in the healing of chronic wounds such as:

- Skin ulcerations due to diabetes, venous stasis, post-surgical infections and gangrenous lesions,
- Decubitis ulcers (bedsores),
- Amputations/infected stumps,
- Skin grafts,
- Burns, and
- Frostbite

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

Daniel Kraemer M/M
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112634