

8.0 510k Statement or Summary

APR 27 2012

510(k) SUMMARY FOR EPIFLO

1. SPONSOR

Neogenix, LLC DBA Ogenix
3401 Enterprise Pkwy, Suite 340
Beachwood, OH 44122

Contact Person: Srinivasan (Sarang) Sarangapani, President
Telephone: 781-702-6732

Date Prepared: April 26, 2012

2. Device Name

Proprietary Name: EPIFLO System
Common/Usual Name: Transdermal continuous Oxygen Therapy System
Classification Name: Topical oxygen chamber for extremities 21 CFR
878.5650 – Class II (Special Controls)

3. PREDICATE DEVICES

Oxybox System – K023456

4. DEVICE DESCRIPTION

EPIFLO is an oxygen delivery system that incorporates a disposable oxygen concentrator. It consists of (1) the oxygen concentrator, and (2) the sterile cannula. The oxygen concentrator is a single patient, single use, disposable, battery-operated device that is capable of delivering 98 to 100 percent oxygen continuously for seven or fifteen days (depending on the model) at a rate of ~3.0 ml/hour. The cannula conveys the oxygen from the oxygen concentrator to the area beneath the bandage overlying the wound.

5. INDICATIONS FOR USE

The EPIFLO System is intended to provide topical oxygen to treat 1) skin ulcerations due to diabetes, venous stasis, post-surgical infections and gangrenous lesions, 2) pressure ulcers, 3) amputations/infected stumps, 4) skin grafts, 5) burns, and 6) frostbite.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The predicate device OxyBox as well as the current device EPIFLO delivers oxygen to the wound at ambient pressure (typically 1 atmosphere). The predicate devices as well as the EPIFLO deliver near 100 percent pure oxygen to the wound site at a rate of ~ 3 mL/hr). Both the Predicate OxyBox and the EPIFLO are single patient, single use disposable devices.

7. PERFORMANCE TESTING

Testing was conducted to validate that the EPIFLO performed according to its specifications. These tests included performance testing for oxygen delivery per the specification for labeled durations, EMC compatibility and sterilization validation.



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

Neogenix, LLC
% Srinivasan Sarangapani, Ph.D.
President
3401 Enterprise Parkway, Suite 340
Beachwood, Ohio 44122

APR 27 2012

Re: K120764
Trade/Device Name: EPIFLO System
Regulation Number: 21 CFR 878.5650
Regulation Name: Topical oxygen chamber for extremities
Regulatory Class: II
Product Code: KPJ
Dated: April 4, 2012
Received: April 6, 2012

Dear Dr. Sarangapani:

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.

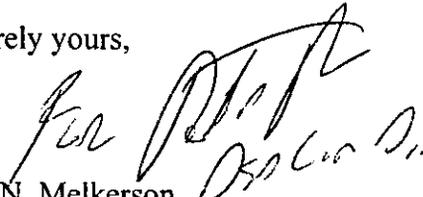
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (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 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,


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): K120764

Device Name: EPIFLO System

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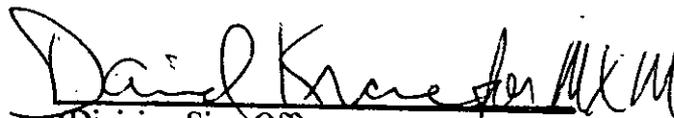
Prescription Use X
(Part 21 CFR 801 Subpart D)

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)



(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120764