December 13, 2019

Neogenix, LLC dba Ogenix
Srinivasan Sarangapani
President
3401 Enterprise Pkwy, Suite 340
Beachwood, Ohio 44122

Re: K190742
Trade/Device Name: EPIFLO-28
Regulation Number: 21 CFR 878.5650
Regulation Name: Topical Oxygen Chamber For Extremities
Regulatory Class: Class II
Product Code: KPJ
Dated: November 12, 2019
Received: November 12, 2019

Dear Srinivasan 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. 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,

Kimberly M. Ferlin, Ph.D.
Assistant Director (acting)
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190742

Device Name
EPIFLO-28

Indications for Use *(Describe)*
The EPIFLO-28 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

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 FOR EPIFLO-28

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: December 13, 2019

2. Device Name

Proprietary Name:	EPIFLO-28
Common/Usual Name:	Transdermal continuous Oxygen Therapy System
Classification Name:	Topical oxygen chamber for extremities 21 CFR 878.5650 – Class II (Special Controls)
Product Code:	KPJ

3. PREDICATE DEVICES

EPIFLO System – K120764

4. DEVICE DESCRIPTION

EPIFLO-28 is an oxygen delivery device 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 twenty eight days 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-28 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 EPIFLO System (7 & 15 day models) as well as the current model EPIFLO-28 delivers oxygen to the wound at ambient pressure (typically 1 atmosphere). The predicate devices as well as the EPIFLO-28 deliver near 100 percent pure oxygen to the wound site at a rate of ~ 3 mL/hr). Both the Predicate EPIFLO 7 & 15 day models and the EPIFLO-28 are single patient, single use disposable devices. The Membrane Electrode Assembly in the EPIFLO-28 is the same as used in the predicate device EPIFLO System (7&15 day models).

The predicate device provides continuous oxygen for 15 days, whereas EPIFLO-28 provides continuous oxygen for 28 days. The predicate device uses different blinking rates of the red indicator light to indicate normal operation and end of life. EPIFLO-28 has two indicator LEDs (green and red) to indicate normal operation and error state and/or end of life. There is no error state indication in the predicate device. EPIFLO-28 has the same footprint as the predicate device, but is taller by quarter of an inch. The delivery cannula was changed from the predicate.

7. PERFORMANCE TESTING

Testing was conducted to validate that the EPIFLO-28 performed according to its specifications. These tests included performance testing for oxygen delivery per the specification for labeled durations, LED operation verification and EMC compatibility. Test methods were the same or more as used in the predicate device.

Biocompatibility testing for EPIFLO-28 enclosure (permanent contact with intact skin) included: cytotoxicity, sensitization, and irritation; for the oxygen delivery cannula (permanent contact with breached/compromised skin) the tests included: cytotoxicity, sensitization, irritation, and material mediated pyrogenicity. In addition, the cannula was subjected to an extractable/leachable analysis. A toxicological risk assessment was performed on the chemical compounds identified in the extractables/leachables testing; no chemical compound was detected above the conservative threshold of toxicological concern. To address the local tissue response to the delivery cannula, a clinical study evaluated wounds exposed to the delivery cannula through wound measurements, wound fluid, and tissue punch biopsies collected weekly for 4 weeks. The wound fluid and punch biopsies were evaluated for pro-inflammatory cytokines, proteases, and macrophages and the results demonstrated a reduction in pro-inflammatory cytokines, proteases, and macrophages at the Week 4 follow up.

To address usability in the home environment, patients (n = 61) in a clinical study used the predicate device for up to 12 weeks. At each visit, patients answered questions in the case report forms about any issues with using the device. A usability study was also conducted with the subject device to evaluate lay user (n = 17) and healthcare professional (n = 18) user experience with the EPIFLO-28.

8. CONCLUSIONS

EPIFLO-28 delivers the same oxygen therapy as the predicate device, but does so for a longer period before replacement is required. It also has the same risk/benefit profile as the predicate. Based on these facts, and based on the results of the performance tests and clinical validation performed by Ogenix, it is concluded that EPIFLO-28 is as safe and as effective as the predicate device.