



June 22, 2018

XVIVO Perfusion AB
% Kathleen Johnson
President
Medical Device Approvals, Inc.
P.O. Box 421
Fairfield, Iowa 52556

Re: K170826
Trade/Device Name: Perfadex Plus
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: Class II
Product Code: KDN
Dated: May 24, 2018
Received: May 25, 2018

Dear Kathleen Johnson:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Carolyn Y. Neuland -S

for

Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K170826

Device Name

Perfadex Plus

Indications for Use (Describe)

Perfadex Plus is indicated for the flushing, static cold storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 7. 510(k) SUMMARY**DATE:** June 22, 2018**SUBMITTER:** XVIVO Perfusion AB
Mässans gata 10
SE-41251 Göteborg
SwedenContact: Kathleen Johnson
Regulatory Affairs Consultant
610-527-0585
kathleen@mdapprovals.com**REGULATION NAME:** Isolated kidney perfusion and transport system and accessories**COMMON OR
USUAL NAME:** Perfadex Plus®**REGULATION
NUMBER** 21 CFR §876.5880**CLASSIFICATION:** Class II**PRODUCT CODE** KDN**PREDICATE DEVICE:** Perfadex® with THAM K091989**DESCRIPTION:** Perfadex® Plus is a pre-buffered, extracellular solution of dextran 40 containing calcium used for rapid cooling, perfusion and storage of lungs in connection with transplantation.**INDICATIONS FOR USE:** Perfadex Plus is indicated for the flushing, static cold storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.**SUBSTANTIAL
EQUIVALENCE:** Perfadex® Plus is substantially equivalent to the predicate Perfadex® with THAM cleared under K091989. The devices have the same intended use.

The differences between Perfadex® Plus and the predicate device Perfadex® with THAM (K091989) are the following:

- The subject device Perfadex® Plus, is buffered with Tromethamine (THAM) and does not require buffering prior use, while the predicate device Perfadex with THAM (K091989) has a slightly acidic pH and requires buffering prior use. The predicate device is supplied with a sterile 50 ml glass bottle containing THAM.
- The subject device Perfadex® Plus contains calcium to further mimic extracellular plasma concentration of electrolytes while the predicate device (K091989) does not contain calcium which is therefore often added at the clinics prior to use.
- Perfadex and Perfadex Plus both are packaged in the Ecobag however the Perfadex Plus Ecobag utilizes the “Click System”

instead of a spike port. The connection to the bag is made with a connector that “clicks” onto the port rather than by inserting a spike into the rubber stopper as in the Perfadex Ecobag. Complete information on the “Click System” can be found in the Device Description.

- Package testing to ensure maintenance of the sterile barrier has been performed according to ISO 11607. The bags have been tested by the manufacturer for bag welding, port system welding, tube welding, and fill volume.

NONCLINICAL TESTING:

Nonclinical testing including biological safety including:

- Cytotoxicity
- Intracutaneous Irritation
- Sensitization
- Hemolysis
- Material Mediated Pyrogenicity
- Leachables

As well as Stability Studies including:

- pH
- Calcium
- Osmolality
- Dextran
- Glucose
- Particulate analysis

Additionally, mechanical testing on the new bag and port system includes:

- Pressure and Leakage testing
- Resistance to dropping
- Penetration testing
- Tensile strength testing
- Flow testing

has shown the changes to the product do not produce any new safety or effectiveness issues.

CLINICAL DATA:

Using a statistically powered sample size with p-values obtained from a federally mandated registry [UNOS] and from a clinical trial, Clinical data on Perfadex® supplemented at point of use with THAM and calcium ions (PTHCa) shows it is substantially equivalent in survival to Perfadex not supplemented with Calcium. Therefore, we can conclude that supplementation with THAM and Calcium does not add any additional risk to patients receiving a lung transplant.

CONCLUSION:

The non-clinical testing conducted as well as clinical data and real-world evidence with the proposed device demonstrate that the proposed device does not raise any new issues of safety and effectiveness and is substantially equivalent to the predicate device.