K091989
Page 1 of 2

XII. PREMARKET NOTIFICATION SUMMARY

OCT 1 2010

Submitted by:	XVIVO Perfusion AB Box 9080 SE-40092 Göteborg SWEDEN
Contact Person:	Mr Kjell Kjörk XVIVO Perfusion AB Box 9080 SE-40092 Göteborg SWEDEN Phone +46 31 721 80 77 Fax +46 31 721 80 90 Mail kkjork@vitrolife.com
Date Prepared:	30 June 2009
Trade Name:	Perfadex® and Perfadex® with THAM
Common Name:	Solution for lung preservation
Classification Name:	Isolated kidney perfusion and transport system and accessories (21 C.F.R. §876.5880)
Predicate Device:	Perfadex® (K000881) and Perfadex® with THAM (K081997)
Description of the Device:	Perfadex® and Perfadex® with THAM is a colloid based "extracellular" low potassium electrolyte solution for rapid cooling, perfusion and storage of lungs in connection with transplantation
Intended Use:	Perfadex® and Perfadex® with THAM is intended for flushing, storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient

Technological Characteristics:

Perfadex® is the only solution which has been specifically developed for lung preservation, and is today used in about 90% of the lung transplantations performed world-wide.

Perfadex® and Perfadex® with THAM is a clear, sterile, non-pyrogenic, colloid based, lightly buffered so called "extracellular" low potassium dextran solution primarily for rapid cooling, perfusion and storage of lungs in connection with transplantation. The solution is slightly acidic (pH 5.5) to permit long shelf life, and is adjusted shortly before use to pH 7.4 by the addition of THAM solution; 1 mmol of THAM per liter of Perfadex®.

Perfadex® was first 510(k) cleared by the FDA on 8 March 2001 (K000881). Perfadex® with co-packed THAM in a pre-filled syringe was cleared on 27 October 2003 (K022730), and then Perfadex® with co-packed THAM in a 50 ml glass bottle was cleared on 9 October 2008 (K081997).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

Mr. Kjell Kjörk
Pharmacist, Senior Regulatory Affairs Manager
XVIVO Perfusion AB
Box 9080
SE-40092 Göteborg
SWEDEN

OCT 1 2010

Re: K091989
Trade/Device Name: Perfadex® and Perfadex® with THAM
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: KDN
Dated: August 30, 2010
Received: September 3, 2010

Dear Mr. Kjörk:

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091989

XI. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K091989

Device Name: Perfadex® and Perfadex® with THAM

Indications for Use:

Perfadex® Solution for Lung Perfusion is indicated for the flushing, storage and transportation of isolated lungs after removal from the donor, in preparation for eventual transplantation into a recipient

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the Counter Use _____
(Per 21 C.F.R. § 801.109)

Carolyn Y Neuland for Herb Lerner, MD.
(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K091989