OCT 09 2008

XII. PREMARKET NOTIFICATION SUMMARY

Submitted by:

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Contact Person:

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Date Prepared: 10 July 2008

Trade Name: 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® (K022730)

Description of the Device: 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® 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:

The device Perfadex® with THAM contains THAM at strength of 3.3 mmol in a sterile 50 ml glass bottle, while the predicate device (K022730) contains THAM at strength of 1.0 mmol in a 1.0 or 2.8 ml pre-filled syringe with THAM.

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® 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 from the co-packed bottle, 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 then cleared on 27 October 2003 (K022730), and this clearance is used as predicate for the current submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 09 2008

Mr. Kjell Kjörk
Pharmacist, Regulatory Affairs Manager
Vitrolife Sweden AB
Faktorvagen 13
Kungsbacka
SWEDEN SE-434 37

Re: K081997
Trade/Device Name: Perfadex® with THAM
Regulation Number: 21 CFR §876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: MSB
Dated: September 10, 2008
Received: September 12, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

XI. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K081997

Device Name: 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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K081997