



Food and Drug Administration  
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March 7, 2016

United Therapeutics Corporation  
Rita Lee, Ph.D., RAC  
Senior Scientist, Regulatory Affairs  
55 TW Alexander Drive, PO Box 14186  
Research Triangle Park, NC 27709

Re: K153384  
Trade/Device Name: Low Potassium Dextran Solution with Tris Diluent  
Regulation Number: 21 CFR§ 876.5880  
Regulation Name: Isolated Kidney Perfusion and Transport System and Accessories  
Regulatory Class: II  
Product Code: KDN  
Dated: (Date on orig SE ltr): November 20, 2015  
Received: (Date on orig SE ltr): November 23, 2015

Dear Rita Lee,

This letter corrects our substantially equivalent letter of February 19, 2016.

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

  
**Benjamin R. Fisher -S**

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)

K153384

Device Name

Low Potassium Dextran Solution with Tris Diluent

Indications for Use (Describe)

Low Potassium Dextran Solution with Tris Diluent is indicated for flushing, 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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## 510(K) SUMMARY

### I. SUBMITTER

United Therapeutics Corporation  
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Research Triangle Park, NC 27709, United States

Phone: 919-485-8350

Fax: 919-313-1298

Contact: Rita Lee, PhD RAC, Senior Scientist, Regulatory Affairs

Date Prepared: November 19, 2015

### II. DEVICE

Name of Device: Low Potassium Dextran Solution with Tris Diluent

Common or Usual Name: Solution for lung preservation

Classification Name: Isolated kidney perfusion and transport system and accessories  
(21 CFR §876.5880)

Regulatory Class: II

Product Code: KDN

### III. PREDICATE DEVICE

Perfadex<sup>®</sup> with THAM, K091989

### IV. DEVICE DESCRIPTION

Low Potassium Dextran (LPD) Solution is a sterile, clear, non-pyrogenic, physiological salt solution for hypothermic flushing, storage, and transportation of human lungs outside the human body. LPD Solution is acidic and is adjusted shortly before use to pH 7.4 by the addition of Tris Diluent.

LPD Solution with Tris Diluent is supplied as 1 liter of LPD Solution in a low density polyethylene (LDPE) bottle (8 per pack), co-packed with one single-use bottle of Tris Diluent. Tris Diluent is also supplied separately in an eight-unit pack. Each container of LPD Solution and Tris Diluent is single-use.

### V. INDICATIONS FOR USE / INTENDED USE

LPD Solution with Tris Diluent is indicated for flushing, storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient. The indications for use and intended use for LPD Solution with Tris Diluent are identical. Both the subject and predicate devices have the same indications for use statement and intended use.

## **VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

LPD Solution with Tris Diluent is substantially equivalent to Perfadex with THAM. LPD Solution with Tris Diluent and Perfadex with THAM have identical intended use. Both LPD Solution and Perfadex are clear, sterile, non-pyrogenic solutions. Perfadex is supplied with THAM, which is added for pH adjustment before use. Similarly, LPD Solution is supplied with Tris Diluent, which is added for pH adjustment before use.

Differences in technological characteristics include packaging, expanded storage conditions, and a change to solution buffering instructions. All technological differences have been evaluated and do not raise any new questions of the safety or effectiveness when compared to the predicate, nor do they affect the safety and effectiveness when compared to the predicate.

## **VII. PERFORMANCE DATA**

Chemical composition testing results have confirmed that LPD Solution and Tris Diluent have the same chemical composition as Perfadex and THAM, respectively.

Results of sterility and pyrogenicity testing on LPD Solution and Tris Diluent have shown that both solutions are sterile with a Sterility Assurance Level (SAL) of  $10^{-6}$  and non-pyrogenic, similar to Perfadex and THAM. Stability testing, including analysis of chemical characteristics, particulate matter, and sterility assessment, has been conducted on LPD Solution and Tris Diluent to verify the shelf life. The results have verified the shelf life for LPD Solution and Tris Diluent, as manufactured and sterilized.

Biocompatibility test results have shown that LPD Solution and LPD Solution after pH adjustment by Tris Diluent meet the requirements of ISO 10993-1.

Results of testing for USP <161> conformance, pH adjustment of LPD Solution with Tris Diluent, verification of fill volume, mechanical requirements, and summative usability testing did not raise any new questions of the safety or effectiveness.

## **VIII. CONCLUSION**

LPD Solution with Tris Diluent has the identical intended use compared to Perfadex with THAM. Evaluation of differences in technological characteristics did not raise any new questions of the safety or effectiveness of LPD Solution with Tris Diluent compared to the predicate device. Therefore, LPD Solution with Tris Diluent is substantially equivalent to Perfadex with THAM.