FEB 2 1 2014

510(k) Summary
Paragonix Sherpa Pak Cardiac Transport System

Submitter:	Paragonix Technologies Inc. c/o Vaughn & Associates 639 Granite Street Braintree, MA02184
Contact Person:	Leo Basta NorthStar Biomedical Associates 93 Benefit Street Providence, RI, 02904 Phone: 617.834.9866 lbasta@northstarbiomedical.com
Date Prepared:	January 7, 2014
Trade Name:	Paragonix Sherpa Pak Cardiac Transport System
Classification Name:	System & Accessories, Isolated Heart, Transport & Preservation
Regulation Number:	21 CFR 876.5880
Product Code:	MSB
Predicate Devices:	Sherpa Pak Cardiac Transport System (K123326) Celsior (K991594)
Device Description:	The Paragonix Sherpa Pak Cardiac Transport System is a device intended to provide a safe, consistent method for cold ischemic storage and transport of donor hearts to recipients for transplantation. The Sherpa Pak System consists of 1) an outer shipper which contains various non-ice based temperature controlled packaging elements. 2) an inner and outer hard shell container (i.e. Sherpa Pak/Sherpa Pak Shell) which provides a double, rigid barrier container in which the heart is immersed and suspended in a Cold Storage Fluid cleared for use in storing and transporting donor hearts and 3) a temperature display and timer to

	monitor temperature and elapsed time of transport, respectively. The changes made to the currently cleared device are labeling changes only. The device subject to this notification is identical to that cleared under K123326.
Intended Use:	Organ storage and preservation for transplantation.
Indications for Use:	The Sherpa Pak Cardiac Transport System is intended to be used for the static hypothermic preservation of hearts during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with the heart. The intended organ storage time for the Sherpa Pak Cardiac Transport System is up to 4 hours. Donor hearts exceeding clinically accepted static hypothermic preservation times should be evaluated by the transplant surgeon to determine transplantability in accordance with accepted clinical guidelines and in the best medical interest of the intended recipient.
Functional Testing:	The premarket notification was submitted for a labeling change to the device. The device did not change in any respect otherwise. The testing performed in support of the original 510(k) continues to be supportive of the modified device.
Summary of Substantial Equivalence:	The design, intended use, principles of operation, and technological characteristics of the Sherpa Pak Cardiac Transport System are substantially equivalent to the previously cleared Sherpa Pak Cardiac Transport System. The labeling change does not alter the device's intended use. There were no changes to the device itself and it is identical to the device cleared under K123326.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 21, 2014

Paragonix Technologies, Inc.
% Leo Basta
Owner
NorthStar Biomedical Associates
93 Benefit Street
Providence, RI 02904

Re: K133432
Trade/Device Name: Paragonix Sherpa Pak Cardiac Transport System
Regulation Number: 21 CFR§ 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: MSB
Dated: January 7, 2014
Received: January 10, 2014

Dear Leo Basta,

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 -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

INDICATION FOR USE

510(k) Number (if known): K133432

Device Name: Paragonix Sherpa Pak Cardiac Transport System

Indications for Use:

The Sherpa Pak Cardiac Transport System is intended to be used for the static hypothermic preservation of hearts during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with the heart.

The intended organ storage time for the Sherpa Pak Cardiac Transport System is up to 4 hours.

Donor hearts exceeding clinically accepted static hypothermic preservation times should be evaluated by the transplant surgeon to determine transplantability in accordance with accepted clinical guidelines and in the best medical interest of the intended recipient.

Prescription Use: ____X____ AND/OR Over-The Counter Use: _____

(Per 21 CFR 801 Subpart D)..... (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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