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510(k) SUMMARY

1) Submitter Information

Justec Medical Products, Inc.
1724 Church St. Holbrook, NY 11741

Establishment registration number:	2436793
Phone #:	516-563-1851 ext. 227
FAX #:	516-563-6509
Contact person:	Jeffrey L. Rothman

2) Device Names

Classification Name:	Isolated kidney perfusion and transport system and accessories (21 CFR 876.5880)
Common/Usual name:	Kidney transporter with disposable cassette
Proprietary name:	HPA, Portable kidney perfusion system

3) Predicate Devices

MOX-100 Renal Preservation System TM2 Transport Module, A pre-amendment device.

4) Device Description

The HPA Portable Kidney Transport System is a patented, self contained renal preservation system that provides the benefits of machine perfusion with a simplified perfusion circuit. The device provides low flow pulsatile perfusion with regulated arterial pressure limits. Audio and visual alarms are provided for over pressure, over temperature, pump failure, tubing failure, and battery failure conditions.

5) Intended Use

The HPA Portable Kidney Transport System is intended for preserving and transporting kidneys for transplant.

6) Comparison of Technological Characteristics

The HPA operates without a membrane oxygenator at lower temperatures, pressures, and pulse rates than the MOX-100. The MOX-100 has provision for oxygen and carbon dioxide tanks, a gas mixer and gas flow controls for mixing of gases with ambient athmosphere. These features are generally not used in clinical practice.

Three studies were performed on mogrel dogs to determine the efficacy of the HPA as compared to the MOX-100. In the studies kidneys were removed, preserved for 24, 72, and 120 hours, and re-perfused by test animals. The kidneys were then evaluated based on blood flow, urine output, creatinine levels, and subsequent microscopic examination after the animals were sacrificed. These studies demonstrate the HPA preserves canine kidneys as well as the MOX-100 for preservation lasting between 24 and 72 hours. For preservation lasting 120 hours the HPA protects the microcirculation better than the MOX-100.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 1999

Mr. Jeffrey Rothman
Justec Medical Products, Inc.
1724 Church Street
Holbrook, NY 11741

Re: K990229
HPA Portable Kidney Preservation System
Model J-1000-1
Dated: August 18, 1999
Received: August 20, 1999
Regulatory Class: II
21 CFR 876.5880/Procode: 78 KDN

Dear Mr. Rothman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K990229

Device Name: HPA Portable Kidney Preservation System Model J-1000-1

Indications for Use:

The HPA Portable Kidney Preservation System, Model J-1000-1 is to be used when prescribed by a physician for the use of storing and preserving a human kidney

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990229/S 001