DEC 10 1999

510(k) Summary

Custodiol® HTK Solution

Common/Classification Name: Isolated Kidney Perfusion and Transport System and Accessories, 21 CFR 876.5880

Dr. Franz Kohler Chemie GmbH
Postfach 1117
D-64659 Alsbach-Hahnlein
Germany

Contact: E. Schaffner, M.D. Prepared: June 16, 1999

A. LEGALLY MARKETED PREDICATE DEVICES

The **Custodiol HTK Solution** is substantially equivalent to the Viaspan Belzer UW Cold Storage Solution, which was cleared by FDA as K944866 on 04 April 1996.

B. DEVICE DESCRIPTION

The HTK solution is intended for perfusion and flushing donor kidneys prior to removal from the donor and for preserving the kidney during hypothermic storage and transport to the recipient. HTK solution is based on the principle of inactivating organ function by withdrawal of extracellular sodium and calcium, together with intensive buffering of the extracellular space by means of histidine/histidine HCl, so as to prolong the period for which the organs will tolerate interruption of blood and oxygen supply. Only a small portion of the osmolality of the HTK solution is due to the sodium and potassium. The composition of HTK is similar to that of extracellular fluid. All of the components of the HTK solution occur naturally in the body.

The HTK solution is relatively low in potassium concentration so that residual solution in the transplanted organ poses no danger to the recipient. This is particularly important in organs that take up relatively large amounts of the perfusate, which may find its way into the recipient's circulation.

The HTK solution has a low viscosity, even at low temperatures. This characteristic assures rapid flow rates during initial perfusion, allowing the organ to be quickly cooled.

C. INDICATIONS FOR USE

Custodiol HTK Solution is indicated for perfusion and flushing donor kidneys prior to removal from the donor or immediately after removal from the donor. The solution is left in the organ vasculature during hypothermic storage and transportation (not for continuous perfusion) to the recipient.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **Custodiol HTK Solution** is a medical device, and it has a similar indications for use as the legally marketed predicate device. While the indications for use statement is not identical to that of the predicate device, the intended use is clearly the same.

The **Custodiol HTK Solution** has the same technological characteristics as the predicate devices. However, the characteristics may not be sufficiently precise to assure equivalence through a point by point comparison. Therefore, extensive clinical data has been collected by the sponsor and others. The performance data clearly demonstrates equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

Both the Custodiol HTK Solution and the predicate device are solutions containing electrolytes, buffering agents, and other materials occurring naturally in the body. Both solutions are intended to reduce metabolism and preserve physiological conditions of explanted organs and tissue during cold storage.

F. TESTING

Several clinical studies have been reported that compared the performance of Custodiol HTK Solution with the Viaspan Belzer UW Solution. These studies have compared survival rates and other outcome measures. The primary evidence for the equivalence of Custodiol and UW solutions has come from the 47-center randomized clinical study carried out under the guidance of the Eurotransplant organization of Leiden, The Netherlands. Over a thousand kidneys were included in the study.

This study showed that the HTK solution performs as well as the UW solution and significantly better than EC solution for kidney transplants. The overall kidney survival rates from the 47-center study for HTK versus UW at four time points were:

	HTK	UW
1 Month	91%	91%
12 Months	83%	82%
24 Months	77%	74%
36 months	74%	68%

G. CONCLUSIONS

The clinical and other performance data amply demonstrate that Custodiol performs as well as the predicate device. This pre-market submission demonstrates Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 1999

Dr. Franz Kohler Chemie GmbH
c/o T. Whit Athey, Ph.D.
Senior Consultant
C.L. McIntosh & Associates, Inc.
Medical & Regulatory Affairs Services
12300 Twinbrook Parkway, Suite 625
Rockville, MD 20852

Re: K992209
Custodiol® HTK Solution
Dated: October 21, 1999
Received: October 21, 1999
Regulatory Class: II
21 CFR §876.5880/Procode: 78 KDN

Dear Dr. Athey:

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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K992209

Device Name: Custodiol HTK Solution

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992209/S001