

FEB 28 2005

## 510(k) Summary

### Custodiol® HTK Solution

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

Dr. Franz Köhler Chemie GmbH  
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Germany

Contact: E. Schaffner, M.D. Prepared: December 14, 2004

#### A. LEGALLY MARKETED PREDICATE DEVICES

For its indication for use, the **Custodiol HTK Solution** is substantially equivalent to the Belzer UW Cold Storage Solution, which was cleared by FDA as K944866 on 04 April 1996 for the multiple indication of kidney, liver, and pancreas preservation. For its specific formulation and other physical and chemical characteristics, it is substantially equivalent to the currently marketed **Custodiol** product as cleared under K992209 and K020924.

#### B. DEVICE DESCRIPTION

The HTK solution is intended for perfusion and flushing donor kidney, liver, heart, and pancreas prior to removal from the donor and for preserving these organs 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.

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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, liver, pancreas, and heart 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 devices. While the indications for use statement is not identical to those of the predicate devices, 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 and animal 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 UW Solution, and others. These studies have compared survival rates and other outcome measures. The primary evidence for the equivalence in effectiveness of Custodiol to that of UW has come from a small number of independent clinical studies.

#### 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.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Dr. F. Köhler Chemie GmbH  
c/o T. Whit Athey, Ph.D.  
Senior Consultant  
Health Policy Resources Group, LLC  
2305 Gold Mine Road, Suite 200  
BROOKVILLE MD 20833-2233

Re: K043461  
Trade/Device Name: Custodiol® HTK Solution for Perfusion and Flushing of Donor Pancreata  
Regulation Number: 21 CFR §876.5880  
Regulation Name: Isolated kidney perfusion and transport system and accessories  
Regulatory Class: II  
Product Codes: 78 KDL and MSB  
Dated: December 14, 2004  
Received: December 15, 2004

Dear Dr. Athey:

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 (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 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.

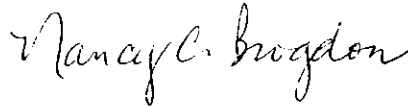
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K043461

Device Name:

Indications For Use:

Custodiol HTK Solution is indicated for perfusion and flushing donor kidneys, liver, pancreas, and heart 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.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

~~AND/OR~~

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David H. Simpson  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K043461