

APR - 5 2004

510(k) Summary

Custodiol® HTK Solution

Common/Classification Name: Isolated Heart 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: September 5, 2003

A. LEGALLY MARKETED PREDICATE DEVICES

For its indication for use, the **Custodiol HTK Solution** is substantially equivalent to the Celsior Cold Storage Solution, which was cleared by FDA as K991594 for the single indication of heart preservation. For its specific formulation and other physical and chemical characteristics, it is substantially equivalent to the currently marketed **Custodiol** product.

B. DEVICE DESCRIPTION

The HTK solution is intended for perfusion and flushing donor hearts prior to removal from the donor and for preserving the heart 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

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organ to be quickly cooled.

C. INDICATIONS FOR USE

Custodiol HTK Solution is indicated for perfusion and flushing donor kidneys, livers, and hearts 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 Celsior Solution, the Viaspan Belzer 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 Celsior has come from a small randomized clinical study and from the extensive experience of the largest heart transplant center in the world.

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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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c/o T. Whit Athey, Ph.D.
Senior Consultant
The Health Policy Resources Group, LLC
2305 Gold Mine Road, Suite 200
BROOKEVILLE MD 20833-2233

Re: K032794

Trade/Device Name: Custodiol® HTK Solution for Perfusion and Flushing of Donor Hearts
Regulation Number: 21 CFR §876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: 78 MSB
Dated: January 21, 2004
Received: January 21, 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 (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); 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K032794

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 x
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Amyc Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032794

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