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510(k) Summary

H&S-Conductivity Standard Solution

510(k) Summary:	This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 C.F.R § 807.92
Submitted by:	H&S Technical Services 1833 W Main St. Ste 119 Mesa AZ. 85201 Phone: 480-517-4918 Fax: 480-517-4924
Contact Person:	John Hyte Email: jchyte@hstechsvc.com
Date Prepared:	February 18, 2004
Product Classification:	Device Name: H&S-Conductivity Standard Solution Common Name: Conductivity Standard Solution Classification Name: Solution-Test Standard-Conductivity, Dialysis Device Classification: II Regulation Number: 21 CFR § 876.5820 Product Code: FKH Panel: GASTROENTEROLOGY
Predicate Device:	Predicate Device 1 Name: Conductivity Standard Solution - MeterCare Manufacturer: IBP Instruments GmbH Sutelstr. 7A 30659 Hanover Germany 510(k) Number: K032075 Predicate Device 2 Name: Conductivity/TDS Calibrator Solution Manufacturer: Mesa Laboratories, Inc. 12100 West 6th Ave. Lakewood, CO 80228 510(k) Number: K033330

510(k) Summary

Device Description:	H&S - Conductivity Standard Solution is salt-based liquid produced by dissolving reagent grade salt in treated water and equilibrated to atmospheric CO_2. The salt concentration determines the conductivity value. The solution is packaged in various size polyethylene bottles and sealed with a taper indicator seal and cap. The product label is added, and the device is placed in a clear plastic bag The product label contains instructions for use, warnings, and other safety information. H&S - Conductivity Standard Solution is available in of a range sizes, values and accuracies.
Indications for Use:	H&S - Conductivity Standard Solutions are a secondary standard solution used for the calibration of conductivity cells together with conductivity meters; which may include meters and cells used by the hemodialysis technician to verify or calibrate conductivity functions of dialysis equipment. These solutions are used remotely from the hemodialysis machine or water purification equipment and do not come in contact with the patient. Conductivity Standard Solution is for In-Vitro Use Only.
Performance Specifications	The manufacturing process of H&S-Conductivity Standard Solution is performed in accordance with the Quality System regulation as specified for medical devices. This quality program addresses the complete production process and post production auditing and customer notification, if needed. H&S - Conductivity Standard Solution is traceable to NIST (National Institute of Standards and Technology). H&S-Conductivity Standard Solution is not sterile and is not marketed as sterile. H&S - Conductivity Standard Solution presents no safety or hazard risk to other devices, personnel or the environment, when used in accordance with the directions outlined in remote meter user directions and the instructions for use.

510(k) Summary

Non-clinical performance:	Verification and validation of the performance specifications of the device was performed on production lots and samples of the two predicate devices. The test results demonstrated that the devices were well below the acceptance specifications. The following standards were used or referenced in the development, production and testing of the H&S - Conductivity Standard Solution: • ANSI/AAMI/ISO 14971A1: Jun 2003 Medical Devices – Risk Management • ISO 10012-1: Quality assurance requirements for measuring equipment • NIST Special Publication 260-142 Feb 2000 Primary Standards and Standard Reference Materials for Electrolyte Conductivity • IUPAC Standards for Conductivity • OIML Standards for Conductivity • ASTM Stand Test Methods D1125-95 Standard Test Methods for Electrical Conductivity and Resistively of Water • ISO 7888-85 E • Water Quality: Determination of Electrical Conductivity • FDA Quality System Regulations (QSR) 21 CFR § 820
Technological Characteristics:	H&S - Conductivity Standard Solution is similar to the predicate devices in that they are all used for calibrating conductivity measurement instruments and are salt-based liquid produced by dissolving reagent grade salt in treated water and then equilibrated to atmospheric CO_2. The salt concentration determines the conductivity value. The solutions are packaged in various sizes of polyethylene bottles They are different in that the predicate device manufacturers make ranges common for use with their specific conductivity meters. H & S provides ranges and salt compositions to meet a broader range of conductivity meters available in the market place.
Conclusion:	It is concluded that the proposed "H&S-Conductivity Standard Solution" is safe and effective for the intended use and is substantially equivalent to the predicate devices. This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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H & S Technical Services
c/o Ms. Laura Danielson
Responsible Third Party Official
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K041636
Trade/Device Name: H&S – Conductivity Standard Solution
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 FKH
Dated: June 16, 2004
Received: June 17, 2004

Dear Ms. Danielson:

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

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): K041636

Device Name: H&S – Conductivity Standard Solution

Indications For Use:

"H&S - Conductivity Standard Solutions" are a secondary standard solution used for the calibration of conductivity cells together with conductivity meters; which may include meters and cells used by the hemodialysis technician to verify or calibrate conductivity functions of dialysis related equipment.

These solutions are used remotely from the hemodialysis machine or water purification equipment and do not come in contact with the patient.
Conductivity Standard Solution is for In-Vitro Use Only.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041636