K032075

SEP 17 2003

IBP

510(k) Summery

Conductivity Standard Solution - MeterCare

1. **Submitted by:**

IBP Instruments GmbH
Sutelstr. 7A
30659 Hannover
Germany
Phone +49 511 651647
Fax +49 511 652283
eMail pfingstmann@ibpmt.com
Internet: www.ibpmt.com

2. **Contact Person:**

Dipl. Ing Werner Pfingstmann

3. **Date Prepared:**

February 10, 2003

4. **Product Classification:**

Device Name:	Conductivity Standard Solution - MeterCare
Common Name:	Standard Solution Conductivity for Dialysis
Classification Name:	SOLUTION-TEST STANDARD-CONDUCTIVITY, DIALYSIS
Regulation Number:	876.5820
Product Class:	II
Product Code:	FKH
Panel:	Advisory Committee Gastroenterology

5. **Predicate Device:**

STANDARD SOLUTION OF KNOWN CONDUCTIVITY
510(k) Number: K851362

RNA MEDICAL CORP
21 CUMMINGS PARK
SUITE 228
WOBURN, MA 01801

6. Device Description

The "Conductivity Standard Solution – MeterCare" is a range of high accuracy conductivity standard solutions to calibrate conductivity meters used in dialysis to test the conductivity of dialysate of dialysis machines and water used in hemodialysis applications.

The Range of solution include:

Nominal Value at 25°C	Salt Composition	Uncertainty Primary solutions	Uncertainty Secondary solutions
46.7 uS/cm	442	±0.10%	±0.15%
70 us/cm	KCl	±0.10%	±0.15%
150 uS/cm	KCl	±0.10%	±0.15%
229 uS/cm	442	±0.10%	±0.15%
445 uS/cm	442	±0.10%	±0.15%
700 uS/cm	442	±0.10%	±0.15%
1000 uS/cm	442	±0.10%	±0.15%
1417 uS/cm	KCl	±0.10%	±0.15%
2060 uS/cm	KCl	±0.10%	±0.15%
3900 uS/cm	KCl	±0.10%	±0.15%
12.50 mS/cm	NaCl	±0.10%	±0.15%
13.40 mS/cm	NaCl	±0.10%	±0.15%
14.00 mS/cm	NaCl	±0.10%	±0.15%
100 mS/cm	NaCl	±0.10%	±0.15%
140 mS/cm	NaCl	±0.10%	±0.15%
190 mS/cm	NaCl	±0.10%	±0.15%

442 Natural Water™ Standard Solutions

The 442™ is a trademark of the Myron L Instruments. The composition is a combination of salts mixed with deionized water and 40% Sodium Sulfate, 40% Sodium Bicarbonate and 20% Sodium Chloride.

7. Indication for use

The "Conductivity Standard Solution – MeterCare" may be used to calibrate conductivity reference meters used to test the dialysate, dialysate concentrate and water treatment systems used with dialysate delivering systems.
MeterCare is an Over-the-Counter product and needs no prescription. The product is for In Vitro use only.

The indication for use "Conductivity Standard Solution – MeterCare" is substantial identical to the predicate device

8. Test:

The following standards were used in testing the Conductivity Standard Solution - MeterCare:

- EN 1441 - Risk Analysis - Medical Devices (1997)
- ISO/DIS 14971: Feb. 2000 Medical Devices - Risk Management
- ISO 10012-1: Quality assurance requirements for measuring equipment
- NIST Special Publication 260-142
  Primary Standards and Standard Reference Materials for Electrolyte Conductivity
- IUPAC Standards for Conductivity
- OIML Standards for Conductivity
- ASTM D 1125-91
  Standard Test Methods for Electrical Conductivity and Resistivity of Water
- ISO 7888
  Water Quality; Determination of electrical conductivity

9. Conclusion:

It is concluded that the proposed "Conductivity Standard Solution – MeterCare" is safe and effective for the intended use and is substantially equivalent to the predicate device.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.'

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2003

IBP Instruments GmbH
c/o Mr. Olaf Teichert
TÜV Product Service GmbH
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K032075
Trade/Device Name: IBP Conductivity Standard Solution – MeterCare, 32.x
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 FKH
Dated: September 2, 2003
Received: September 5, 2003

Dear Mr. Teichert:

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 Statement

510(k) Number K032075

Device Name: Conductivity Standard Solution - MeterCare

Indication for Use:

The "Conductivity Standard Solution – MeterCare" may be used to calibrate conductivity reference meters used to test the dialysate, dialysate concentrate and water treatment systems used with dialysate delivering systems.
MeterCare is an Over-the-Counter product and needs no prescription. The product is for In Vitro use only.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)
Concurrence of CDRH, Office Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032075