Premarket Notification 510(k)

Summery

HDM97
Dialysis Meter

June 22, 2001

Applicant's and manufacturing address

IBP Instruments GmbH
Sutelstr. 7A
30659 Hannover
Germany

Dipl. Ing Werner Pfingstmann

Phone +49 511 651647
Fax +49 511 652283

Werner Pfingstmann

Substantial Equivalence

Predicate Device

Neo2 meter - 510(k) Number: K992431

Automata Instrumentation, Inc.
7830 East Redfield Road #12
Scottsdale, Arizona 85260 USA

Description of the device

The HDM97 was developed in 1997 to test conductivity/temperature, pressure and pH in hemodialysis applications.

The HDM97 has a large, easy readable 3½ Digital Liquid Crystal Display. It comes with a waterproof key membrane. All selections are done with 9 key's including *On* and *Off*.
The software is designed to be logical and easy to use for the user either safe and precise in measurement.

Intended use

The HDM97 may be used by hemodialysis personnel to test the conductivity, temperature, pressure and pH of the dialysate solution used with hemodialysis delivering systems.
The HDM97 may also be used to test the conductivity/temperature and pH of acid and sodium bicarbonate dialysate concentrates and water used in hemodialysis applications.

Technological characteristics HDM97 – Predicate device

Comparsion Table

	Neo2 meter	HDM97
Measuring		
Conductivity	Yes	Yes
Temperature	Yes	Yes
Pressure	Yes	Yes
pH	Yes	Yes
Microprocessor controlled	Yes	Yes
RS232-Interface	No	Yes
Power supply	Battery	Rechargeable Battery

The technological characteristics of the HDM97 and the predicate device are completely identical.

Additional

In over 17 years of developing, manufacturing, marketing and servicing meters for dialysis, no adverse incidents have ever been reported to us involving patient's or staff safety. The safety inherent in the design has been well thought out, and proven by the documented, historical reliability of meters used by the market for many years.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2002

IBP Instruments GMBH
c/o Mr. Mark Job
TPR Project Manager
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K020908
Trade/Device Name: HDM 97 (non-remote conductivity meter)
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 FIZ
Dated: May 6, 2002
Received: May 7, 2002

Dear Mr. Job:

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 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:

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" (21 CFR Part 807.97). 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 _____

Device Name: HDM97

Indication for Use:

The HDM97 may be used by hemodialysis personnel to test the conductivity, temperature, pressure and pH of the dialysate solution used with hemodialysis delivering systems.
The HDM97 may also be used to test the conductivity/temperature and pH of acid and sodium bicarbonate dialysate concentrates and water used in hemodialysis applications.

(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)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020908