510(k) Summery
HDM99

1. **Submitted by:**
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2. **Contact Person:**
Dipl. Ing Werner Pfingstmann

3. **Date Prepared:**
November 15, 2001

4. **Product Classification:**
Device Name: HDM99
Common Name: Conductivity/Temperature/Pressure/pH multitest meter
Classification Name: Meter, Conductivity, non-remote 78FIZ

5. **Predicate Device:**
Neo2 meter - 510(k) Number: K992431
Automata Instrumentation, Inc.
7830 East Redfield Road #12
Scottsdale, Arizona 85260 USA

6. **Device Description**
The HDM99 was developed in 1990. The first version was called HDM90.
1996 we added the Flow measurement. From this time on the device was called HDM96.
1999 we increased accuracy and software functionality. The device was renamed to HDM99.
The HDM99 has a large, easy readable Graphic Liquid Crystal Display. It comes with a waterproof key membrane. All selections are done with 22 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.
The HDM99 has a RS232-Interface for the possibility to collect and visualize data on a PC.
The software is designed to be logical and easy to use for the user either safe and precise in measurement.

7. **Indication for use:**

The HDM99 may be used by hemodialysis personnel to test the conductivity, temperature, pressure, pH and flow of the dialysate solution used with hemodialysis delivering systems.
The HDM99 may also be used to test the conductivity/temperature and pH of acid and sodium bicarbonate dialysate concentrates and water used in hemodialysis applications.
The HDM99 may also be used to test the voltage and alternating signals in hemodialysis delivering systems.

K020904

The indication for use for the HDM99 Dialysis Meter is similar to the predicate device Neo2 meter, K992431

8. Test:

The following standards were used in testing the HDM99 Dialysis Meter:

- EN 1441 - Risk Analysis - Medical Devices (1997)

- IEC 60601-1-4: 1996
  Medical Electrical Equipment,
  Part 1: General Requirements for Safety;

- IEC 601-1:1988 Medical Electrical Equipment,
  Part 1: General Requirements for Safety

- ISO/DIS 14971: Feb. 1999
  Medical devices - Risk Management

9. Conclusion:

It is concluded that the proposed HDM99 Dialysis Meter 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

MAY 2 2 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: K020909
Trade/Device Name: HDM 99 (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: HDM99

Indication for Use:

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The HDM99 may also be used to test the voltage and alternating signals in hemodialysis delivering systems.

(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 K020904