K100237

MYRON L COMPANY

D-6 Dialysate Meter 510(K) Summary

APR 2 8 2010

1. OWNER/MANUFACTURER

1.1. Myron L Company
2450 Impala Drive
Carlsbad, CA 92010-7226
USA

1.2. Phone: (760) 438-2021

1.3. Fax: (760) 931-9189

1.4. Website" www.myronl.com

2. CONTACT INFORMATION

2.1. Mr. Richard Spahl
Quality Manager
(760) 438-2021 x 1303
rspahl@myronl.com

3. DEVICE NAME

3.1. Trade Name: D-6 Dialysate Meter.™

3.2. Common Name: Digital, handheld, multi-function dialysis meter.

3.3. Classification Name: Meter, Conductivity, Induction, Remote Type.

3.4. Classification Code: FLB.

4. DEVICE DESCRIPTION

4.1. The D-6 Dialysate Meter™ is a microprocessor-based, battery powered, handheld, device that measures conductivity, resistivity total dissolved solids (TDS), pH, Temperature, and oxidation-reduction potential (ORP) of water and dialysate fluids associated with hemodialysis delivery systems.

4.2. It measures and reports multiple ranges of conductivity, resistivity, TDS, pH and ORP.

4.3. All measurement functions are automatically compensated for temperature.

4.4. Up to 100 measurements can be stored in the devices memory, including the measured value, temperature and the date/time the measurement was taken. The device comes in a waterproof, chemically resistant case.

5. INDICATIONS OF USE

5.1. Myron L Company D-6 Dialysate Meter™ is a hand-held, multi-test instruments that is intended for use by trained hemodialysis professionals to verify the characteristics of product water, dialysate and sodium bicarbonate dialysate used with hemodialysis systems as a means of independently verifying functioning of in-line monitors.

5.2. It may also be used by water purification specialist to verify the suitability of feed water used with hemodialysis systems and to test wastewater created by hemodialysis systems.

5.3. D-6 Dialysate Meter is intended for the above uses where:

a. The measurement of conductivity, resistivity, TDS, pH is needed and;

b. The measurement of Oxidation Reduction Potential (ORP) is needed to determine the presence and level of oxidizing or reducing agents in product water or treated wastewater.

6. COMPARISON TO PREDICATE DEVICES

Table 1: D-6 Comparison to Predicate Devices

Feature/Function	DEVICE			
	D-6	Hydra	90XL	HDM97
Measurement Type	Remote	In-Line or Remote	In-Line or Remote	In-Line
Conductivity	YES	YES	YES	YES
pH	YES	YES	YES	YES
Temperature	YES	YES	No	YES
Resistivity[1]	YES	YES	No	No
TDS[1]	YES	YES	No	No
ORP[1]	YES	No	No	No
Pressure	No	No	YES	YES
Temperature Compensated	Automatic All Ranges	Automatic All Ranges	Automatic - Requires External Temp Sensor	Requires Programming
Sensors Type	Built In: Field Replaceable	Built In: Not Replaceable	Separate Accessories	Separate Accessories
Microprocessor Based	YES	YES	YES	YES
Power supply	Battery	Battery	Rechargeable Battery	Rechargeable Battery

[1] Used in water quality measurement only. Generally not use to test/check dialysate.

7. RESULTS OF PERFORMANCE TESTING

7.1. Performance tests were carried out on the D-6 Dialysate Meter™ and the three predicate devices listed in Table 1, above. These tests:

7.1.1. Were performed on side-by-side using identical solutions and test set-ups.

7.1.2. Compared each device to its published specs.

7.1.3. Where possible, compared each device to all of the other devices.

a. Not all of the devices have the same measurement capabilities regarding number and types of parameters as well as range of values covered.

7.2. Clinical Testing:

7.2.1. Clinical Testing was not performed on these devices.

7.3. Biocompatibility:

7.3.1. This type of device does not require biocompatibility testing.

8. SAFETY

8.1. A Risk Analysis and Failure Modes Effects and Criticality Analysis (FMECA) was performed to identify possible sources of hazards to the user or patient related to the use of the device.

8.1.1. All potential risks were found to be acceptable and/or mitigate-able.

9. CONCLUSION:

9.1. The D-6 Dialysate Meter™ is substantially equivalent regarding safety and effectivity to other devices already on the market that have the same intended uses.

9.2. The D-6 Dialysate Meter™ does not pose any new safety risks or effectivity issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6
Silver Spring, MD 20993-0002

Mr. Richard James Spahl
Quality Manager
Myron L Company
2450 Impala Drive
CARLSBAD CA 92010-7226

APR 23 2010

Re: K100237
Trade/Device Name: Dialysate Meter, Model D-6
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FLB
Dated: January 22, 2010
Received: January 26, 2010

Dear Mr. Spahl:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

III. INDICATIONS FOR USE:

510(k) Number (if known): K100237

Device Name: Dialysate Meter, Model D-6

Indications for Use:

Myron L Company D-6 Dialysate Meter™ is a hand-held, multi-test instrument that is intended for use by trained hemodialysis professionals to verify the characteristics of product water, dialysate and sodium bicarbonate dialysate used with hemodialysis systems as a means of independently verifying functioning of in-line monitors.

It may also be used by water purification specialist to verify the suitability of feed water used with hemodialysis systems and to test wastewater created by hemodialysis systems.

D-6 Dialysate Meter is intended for the above uses where:

- The measurement of conductivity, resistivity, TDS, pH is needed and;
- The measurement of Oxidation Reduction Potential (ORP) is needed to determine the presence and level of reducing agents in source water, product water and/or treated wastewater

Prescription Use X (Part 21 CFR 801 Subpart D) and/or Over-The-Counter Use (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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K100237