



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 21, 2015

Mesa Laboratories, Inc.
Jamie Louie
Quality Manager
12100 West 6th Avenue
Lakewood, CO 80228

Re: K150657
Trade/Device Name: Phoenix XL Dialysate Meter
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FIZ
Dated: August 20, 2015
Received: August 21, 2015

Dear Jamie Louie,

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,

Herbert P. Lerner -
S



for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K150657

Device Name: Phoenix XL Dialysate Meter

Indications For Use:

This device is designed for use by hemodialysis professionals to verify the conductivity, temperature, and pH of solutions in the hemodialysis setting.

Prescription Use
 (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)

Page 1 of 1



510(k) Summary

Owner: Mesa Laboratories, Inc.
12100 West 6th Avenue
Lakewood, CO 80228
Phone: (303) 987-8000 FAX: (303) 987-8989

Contact Person: Jamie Louie, Quality Manager

Date: March 11, 2015

Device Name: Phoenix XL Dialysate Meter

Common Name: Meter, Conductivity, Non-Remote

Device Classification: Classification: II
Classification Panels: Gastroenterology
Regulation Number: 21 CFR § 876.5820,
Meter, Conductivity, Non-Remote
Product Code FIZ

Predicate Device(s): Phoenix Dialysate Meter
Mesa Laboratories Inc
510(k) Number K955298
Cleared February 29, 1996

Device Description: This device is a hand-held battery powered, multi-test meter designed for use by hemodialysis professionals to measure the conductivity, temperature and pH of Dialysate solutions associated with the dialysis treatment. The unit houses the conductivity cell, electronic circuitry and digital display. A syringe attaches to the unit with luer connectors. When pulled, the syringe creates a vacuum and draws solution through the conductivity cell for measurement. The conductivity cell contains the conductivity electrodes, a thermistor, and a pH electrode. A 3.6 volt battery provides power.

Indications for Use: This device is designed for use by hemodialysis professionals to verify the conductivity, temperature, and pH of solutions in the hemodialysis setting

Technological Characteristics: The technological Characteristics are summarized in the table below.

Technological Characteristic	Mesa Laboratories, Inc. Predicate Device 1996 510(k) K955298	Mesa Laboratories, Inc. New Device 2013
Intended Use	The Phoenix Dialysate Meter is designed for use by hemodialysis professionals to verify proper conductivity, temperature and pH of solution in the hemodialysis setting.	The Phoenix XL Dialysate Meter is designed for use by hemodialysis professionals to verify proper conductivity, temperature and pH of solution in the hemodialysis setting.
User Instructions	See attached User Manual	See attached User Manual
Conductivity Accuracy	±0.01 mS/cm from 0.10 to 1.99 mS/cm ±0.1 mS/cm from 2.0 to 19.9 mS/cm ±2.0 mS/cm from 20.0 to 119.9 mS/cm ±30.0 mS/cm from 120.0 to 200.0 mS/cm	±0.01 mS/cm from 0.10 to 1.99 mS/cm ±0.1 mS/cm from 2.0 to 19.9 mS/cm ±2.0 mS/cm from 20.0 to 119.9 mS/cm ±5.0 mS/cm from 120.0 to 200.0 mS/cm
Conductivity Resolution	0.01 mS/cm from 0.10 to 1.99 mS/cm 0.1 mS/cm from 2.0 to 19.9 mS/cm 1 mS/cm from 20.0 to 200.0 mS/cm	0.01 mS/cm from 0.10 to 1.99 mS/cm 0.1 mS/cm from 2.0 to 19.9 mS/cm 1 mS/cm from 20.0 to 200.0 mS/cm
Conductivity Temperature Compensation	15°C to 45°C	15°C to 45°C
Temperature Range	15°C to 90°C	15°C to 90°C
Temperature Accuracy	±1°C from 15°C to 90°C	±1°C from 15°C to 90°C
Temperature Resolution	1°C from 15°C to 90°C	1°C from 15°C to 90°C
pH Range	2.0 to 10.0 pH	2.0 to 10.0 pH
pH Accuracy	±0.1 from 2.0 to 10.0 pH	±0.1 from 2.0 to 10.0 pH
pH Resolution	0.1 from 2.0 to 10.0 pH	0.1 from 2.0 to 10.0 pH
Battery Type	522 9VDC Alkaline	3.6 VDC Lithium
Dimensions	H 10" x W 3.3" x T 1"	H 11" x W 2.9" x T 1.7"
Weight	7.33 oz.	10.6 oz. (300g)

The Phoenix XL Dialysate Meter is similar to the predicate device in that they are both hand-held meters, measuring Conductivity, pH, and temperature. Both devices use conductivity cells using electrodes to measure the conductivity, a thermistor to measure temperature and a pH electrode to measure pH. Both devices are battery powered.

Nonclinical
Performance:

Validation of the performance of the device was performed on units equivalent to production.

Conclusions
Drawn from
Demonstrating
Safety and
Effectiveness:

The results of the validations show that the pPhoenix XL Dialysate Meter is equivalent to the pPhoenix Dialysate Meter for measuring Conductivity, pH, and temperature.

The Phoenix XL Dialysate Meter is substantially equivalent to the legally marketed Phoenix Dialysate Meter (predicate device).