MesaLabs

510(k) Summary

APR 1 8 2013

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:	January 28, 2013
Device Name:	Conductivity/pH Calibrator Solution
Common Name:	Combined Standard Solution
Device Classification:	Classification: II Classification Panels: Gastroenterology Regulation Number: 21 CFR § 876.5820, Solution – Test Standard – Conductivity, Dialysis Product Code FKH
Predicate Device(s):	Conductivity/TDS Calibrator Solution Mesa Laboratories Inc 510(k) Number K033330 Cleared February 27, 2004
Device Description:	The device consists of salts (Sodium Chloride, Sodium Phosphate Dibasic, and Potassium Phosphate Monobasic) dissolved in de-ionized water. The proportion of total salt determines the solution's conductivity. The proportions of Sodium Phosphate Dibasic and Potassium Phosphate Monobasic determine the solution's pH. The solution is packaged into sealed polyethylene bottles. The performance specifications of the device are a pH value of pH 7.0 ± 0.03 pH units and a conductivity value of 14.00 mS/cm ± 0.03 mS/cm. The solution should maintain these values for 18 months stored in a sealed bottle. The solution should also maintain these values

for 30 days within an opened but recapped bottle. There will be two bottle sizes of this solution, a 32-oz bottle and a 16-oz bottle.

The solution is composed of the following:

Component	***CAS Registry Number***	***Suppliers***
Sodium Chloride	7647-14-5	Rocky Mountain Reagents VWR Scientific
Sodium Phosphate Dibasic	7558-79-4	Rocky Mountain Reagents Sigma-Aldrich Inc. VWR Scientific
Potassium Phosphate Monobasic	7778-77-0	Rocky Mountain Reagents VWR Scientific
De-ionized Water	7732-18-5	In-House using Water De-ionizer

No components of the device come in contact with the patient.

Indications for Use: Conductivity/pH Calibrator Solutions are a secondary standard solution used for the calibration of conductivity/TDS cells together with conductivity/TDS and pH measurement instruments. The conductivity /TDS cells and instruments may be indicated for calibrating the conductivity and pH measurement function of hemodialysis machines and water purification equipment for hemodialysis, or for verifying proper function of hemodialysis machine or water purification equipment measurement functions. These solutions are used remotely from the hemodialysis machine or water purification equipment, and does not come into contact with the patient.

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

Technological Specification	*Mesa Laboratories, Inc. Predicate Device 2004 510(k) K033330*	*Mesa Laboratories, Inc. New Device 2013*
Conductivity Value	100.0 millisiemen 14.0 millisiemen 13.4 millisiemen 150 microsiemen 1.0 microsiemen	14.0 millisiemen
pH Value	Not Specified* *Measured values ranged 5.1 pH to 7.0 pH	7.0 pH
Accuracy	100.0 millisiemen ±0.2 millisiemen @ 25°C 14.0 millisiemen ±0.02 millisiemen @ 25°C 13.4 millisiemen ±0.02 millisiemen @ 25°C 150 microsiemen ±2 microsiemen @ 25°C 1.0 microsiemen ±2 microsiemen @ 25°C	±0.03 millisiemen @ 25°C ±0.03 pH @ 25°C
Salt Composition (amount)	70. 0g/l NaCl 7.799g/l NaCl 7.443g/l NaCl 48.90mg/l NaCl 0.4915g/l NaCl	4.08g/l NaCl 5.34 g/l Sodium Phosphate Dibasic 2.87 g/l Potassium Phosphate Monobasic
Salt Composition (chemical)	NaCl (Sodium Chloride)	NaCl (Sodium Chloride) Sodium Phosphate Dibasic Potassium Phosphate Monobasic
Ingredients	Sodium Chloride (CAS # 7647-14-5) Water (CAS # 7732-18-5)	Sodium Chloride (CAS # 7647-14-5) Sodium Phosphate Dibasic (CAS # 7558-79-4) Potassium Phosphate Monobasic (CAS # 7778-77-0) Water (CAS # 7732-18-5)
Appearance Properties	Clear, Colorless Liquid Specific Gravity: Approx. 1-1.04	Clear, Colorless Liquid Specific Gravity: Approx. 1-1.04
Chemical Properties	Odor: Odorless Boiling Point: Approx 100.1°C Melting Point: Approx -0.6-0°C Vapor Pressure: <25mmHG @ 25°C Solubility in water" Infinite	Odor: Odorless Boiling Point: Approx 100.1°C Melting Point: Approx -0.6-0°C Vapor Pressure: <25mmHG @ 25°C Solubility in water" Infinite
Bottle Material	HDPE	HDPE
Shelf Life	18 months* *Tests conducted on samples of microsiemen solutions stored over 18 months old showed the solution remained within specification. The original 510(k) submitted had an expiration date of 12-months on microsiemen solutions	18 months Testing of sealed samples showed that pH and conductivity values will remain within the specification after 18 months. Test results were extrapolated from data taken between 13 and 41 weeks.
Shelf Life once bottle is opened	30 days	30 days
Preservative	None	None

Nonclinical Performance:

Validation of the performance of the device was performed on production lots using N.I.S.T. SRM's (Standard Reference Materials) produced in accordance with instructions provided by N.I.S.T. and used as primary calibration standards. The following is a list of the validations performed:

PQ-RM017 pH and Conductivity Solution Manufacturing Process
The purpose of this test was to validate that the device could be produced to specification using the manufacturing process.

PQ-RM018 pH and Conductivity Solution Open Bottle Stability
The purpose of this test was to validate that the device would meet specifications after bottles are opened, exposed to air and then recapped several times. The test results demonstrate that the new device, like the predicate device, is within specification after 30 days of the bottle has been opened and then tightly recapped several times.

PQ-RM019 pH and Conductivity Solution Storage Stability
The purpose of this test was to validate that the device values remain within specification for 18 months. The test results demonstrate that the new device, like the predicate device, is projected to be within specification for 18 months.

PQ-RM020 pH and Conductivity Solution Instrument Independence
The purpose of this test was to validate that the device values are independent upon the type of measurement instrument. The test results demonstrate that the new device, like the predicate, conductivity measurements are independent upon the type of measurement instrument.

Conclusions Drawn from Demonstrating Safety and Effectiveness:

The results of the validations show that the conductivity of the new device when manufacturered, prior to the expiration date, and after the bottle is opened and recapped for 30 days are the same as the predicate values. The tests also showed that different meters will measure the same conductivity values for the new device as the predicate.

The Conductivity/pH Calibrator Solution is substantially equivalent to the legally marketed Conductivity/TDS Calibrator Solution (predicate device) for the intended use as a secondary standard solution used for the calibration of conductivity/TDS cells together with conductivity/TDS measurement instruments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 18, 2013

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

Re: K130100
Trade/Device Name: Conductivity/pH Calibrator Solution
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FKH
Dated: February 1, 2013
Received: February 20, 2013

Dear Ms. 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 contact 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. 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,

Benjamin R. Fisher -S

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): K130100

Device Name: Conductivity/pH Calibrator Solution

Indications For Use:

Conductivity/pH Calibrator Solutions are a secondary standard solution used for the calibration of conductivity/TDS cells together with conductivity/TDS and pH measurement instruments. The conductivity /TDS cells and instruments may be indicated for calibrating the conductivity and pH measurement function of hemodialysis machines and water purification equipment for hemodialysis, or for verifying proper function of hemodialysis machine or water purification equipment measurement functions. These solutions are used remotely from the hemodialysis machine or water purification equipment, and does not come into contact with the patient.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (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)

Benjamin R. Fisher -S
2013.04.18 11:51:41 -04'00'

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130100