FEB 27 2004

510(k) Summary

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.
Submitter	Mesa Laboratories, Inc. 12100 West 6th Ave. Lakewood CO 80228
Contact Person	Todd Romero, QC Manager
Date Prepared	15 October, 2003
Name	Conductivity/TDS Calibrator Solution
Common Name	Solutions Test Standard-Conductivity, Dialysis
Device Classification	Classification: II Classification Panels: Gastroenterology Regulation Number: 21 CFR § 876.5820
Predicate Device(s)	Standard Solution of Conductivity and Measurement RNA Medical Corporation 510(k) Number K851362 Cleared June 12, 1985
Performance Standards	Performance standards have not been established by the FDA under section 514 of the Federal, Food, Drug and Cosmetic Act
Device Description	The device consists of salt dissolved in purified water. The proportion of salt determines the solution's conductivity. The solution is packaged into sealed polyethylene bottles.

Indications for Use	Conductivity/TDS Calibrator Solutions are a secondary standard solution used for the calibration of conductivity/TDS cells together with conductivity/TDS measurement instruments. The conductivity/TDS cells and instruments may be indicated for calibrating the conductivity 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 do not come into contact with the patient.
Technological Characteristics	The Calibrator Solution is similar to the predicate device in that they are both used for calibrating conductivity measurement instruments and both obtain their conductivity value by a controlled quantity of salt dissolved in water. They are different in that the predicate device was only offered in one value of conductivity and was indicated for calibrating one particular meter, while Mesa's solution will be offered in a number of different values and can be used for any conductivity meter.
Nonclinical Performance	Validation of the performance of the device was performed on production lots by the Danish Institute of Fundamental Metrology. The test results demonstrated that the device exceeded the acceptance specifications by greater than one order of magnitude.
Conclusion	Conductivity/TDS Calibrator Solution is substantially equivalent to the legally marketed Standard Solution of Conductivity and Measurement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2004

Mr. Todd Romero
Quality Control Manager
Mesa Laboratories, Inc.
12100 West 6th Avenue
LAKEWOOD CO 80228

Re: K033330
Trade/Device Name: Conductivity/TDS Calibrator Solution
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 FKH
Dated: February 4, 2004
Received: February 5, 2004

Dear Mr. Romero:

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 Section 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 the 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" (21CFR Part 807.97) you may obtain. 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 (if known): K033330

Device Name: Conductivity/TDS Calibrator Solution

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033330

"Confidential"

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)