



August 5, 2019

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

Re: K191496  
Trade/Device Name: TDS Standard Solution  
Regulation Number: 21 CFR 876.5820  
Regulation Name: Hemodialysis system and accessories  
Regulatory Class: II  
Product Code: FKH  
Dated: June 5, 2019  
Received: June 5, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carolyn Y. Neuland, Ph.D.  
Assistant Division Director  
DHT3A: Division of Renal, Gastrointestinal, Obesity  
and Transplant Devices  
OHT3: Office of Gastro-Renal, ObGyn,  
General Hospital and Urology Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K191496

Device Name

TDS Standard Solution

### Indications for Use (Describe)

This TDS Standard Solution is indicated for verifying the accuracy (calibration) of TDS (Total Dissolved Solids) meters. This standard solution should be used immediately before conductivity meters are used to determine the conductivity of water obtained from water purification systems used in hemodialysis. This solution is prepared from a mixture of salts comprised of 40% Sodium Bicarbonate, 40% Sodium Sulfate, and 20% Sodium Chloride which is intended to mimic natural water systems. These solutions are used remotely from the water purification equipment, and do not come into contact with the patient.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 510(k) Summary K191496

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

Contact Person: Jamie Louie, Director of Quality

Date: July 11, 2019

Device Name: TDS Standard Solution

Trade Name: TDS Standard Solution

Common Name: Conductivity/TDS Calibrator Solution

Classification Name: Solution-Test Standard-Conductivity, Dialysis

Device Classification: Classification: II  
Classification Panels: Gastroenterology/Urology  
Regulation Number: 21 CFR § 876.5820,  
Solution-Test Standard-Conductivity, Dialysis  
Product Code 78 FKH

Predicate Device(s): Conductivity/TDS Calibrator Solution  
Mesa Laboratories Inc  
510(k) Number K033330  
Cleared February 4, 2004

Device Description: The device consists of salts (Sodium Chloride, Sodium Bicarbonate and Sodium Sulfate) dissolved in de-ionized water. The solution is packaged into sealed polyethylene bottles.

Indications for Use: This TDS Standard Solution is indicated for verifying the accuracy (calibration) of TDS (Total Dissolved Solids) meters. This standard solution should be used immediately before conductivity meters are used to determine the conductivity of water obtained from water purification systems used in hemodialysis. This solution is prepared from a mixture of salts comprised of 40% Sodium Bicarbonate, 40% Sodium Sulfate, and 20% Sodium Chloride which is intended to mimic natural water systems.

These solutions are used remotely from the water purification equipment, and do not come into contact with the patient.

|                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                     |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| General<br>Description of<br>Diseases or<br>Conditions<br>Device will treat: | The population requiring dialysis requires that the solutions used in the dialysis machine and during the preparation of solutions used in the hemodialysis setting be verified for the proper conductivity. The hemodialysis industry uses conductivity meters to verify the proper conductivity. The new device is used to verify and calibrate these meters at conductivities near the new values of the device. |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                  |                                                                                                                                                                                                                                                                                                                                                                                     |
|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Operational Use: | Prior to operating the conductivity meter, the user draws the Conductivity/TDS Calibrator Solution into the meter or dips the meter sensor into the solution to verify the meter is reading the value of the solution. If meter does not read the correct value (within the tolerances of the solution and the meter), the user will calibrate the meter to read the correct value. |
|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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

|                                                                 |                                                                                                                                                                                                                                                                                              |
|-----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Scientific<br>Concepts that<br>form the basis<br>of the Device: | The conductivity of the fluid is determined by the amount of electrical current flow within the solution. The dissolved salts separate into positive and negative ions. The ions are free to move and the movement resulting from a voltage difference will result in an electrical current. |
|-----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### Modifications to Predicate:

The following modifications were made from the predicate to the new device:

1. Additional Values
2. Use of two different salts

##### 1. Additional Values

The new device has conductivity values of 23.8  $\mu\text{S}/\text{cm}$ , 229  $\mu\text{S}/\text{cm}$  and 2060  $\mu\text{S}/\text{cm}$  are added to the original seven values of the predicate.

##### 2. Use of two additional salts

The new device uses sodium bicarbonate and sodium sulfate in addition to the sodium chloride used in the predicate device.

|                                   |                                                                      |
|-----------------------------------|----------------------------------------------------------------------|
| Technological<br>Characteristics: | The technological Characteristics are summarized in the table below. |
|-----------------------------------|----------------------------------------------------------------------|

| <b>Technological Characteristic</b>            | <b>Mesa Laboratories, Inc. Predicate Device 2004 510(k) K033330</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Mesa Laboratories, Inc. New Device 2019 510(k) K191496</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Intended 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. | This TDS Standard Solution is indicated for verifying the accuracy (calibration) of TDS (Total Dissolved Solids) meters. This standard solution should be used immediately before conductivity meters are used to determine the conductivity of water obtained from water purification systems used in hemodialysis. This solution is prepared from a mixture of salts comprised of 40% Sodium Bicarbonate, 40% Sodium Sulfate, and 20% Sodium Chloride which is intended to mimic natural water systems. These solutions are used remotely from the water purification equipment, and do not come into contact with the patient. |
| User Instructions                              | See attached label                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | See attached label                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Appearance Properties                          | Clear, Colorless Liquid<br>Specific Gravity: Approx. 1- 1.04                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Clear, Colorless Liquid<br>Specific Gravity: Approx. 1- 1.04                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Chemical Properties                            | Odor: Odorless<br>Boiling Point: Approx. 100.1°C<br>Melting Point: Approx. -0.6-0°C<br>Vapor Pressure: <25mmHg @ 25°C<br>Solubility in water: Infinite                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Odor: Odorless<br>Boiling Point: Approx. 100.1°C<br>Melting Point: Approx. -0.6-0°C<br>Vapor Pressure: <25mmHg @ 25°C<br>Solubility in water: Infinite                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Conductivity Values and Specifications at 25°C | 150 ± 2 microsiemen/cm<br>1.0 ± 0.002 millisiemen/cm<br>3.9 ± 0.02 millisiemen/cm<br>12.5 ± 0.02 millisiemen/cm<br>13.4 ± 0.02 millisiemen/cm<br>14.0 ± 0.02 millisiemen/cm<br>100.0 ± 0.2 millisiemen/cm                                                                                                                                                                                                                                                                                                                                                                                                                                        | 23.8 ± 0.2 microsiemen/cm<br>229 ± 2 microsiemen/cm<br>2060 ± 0.02 microsiemen/cm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| TDS Values and Specifications at 25°C          | Not specified                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 15 ppm ± 1%<br>150 ppm ± 1%<br>1500 ppm ± 1%                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Salt Composition                               | NaCl (Sodium Chloride)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | NaCl (Sodium Chloride)<br>Sodium Bicarbonate<br>Sodium Sulfate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Disinfectant                                   | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Bottle                                         | High-density Polyethylene (HDPE)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | High-density Polyethylene (HDPE)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Shelf Life                                     | 18 months                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 18 months                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Open Bottle Shelf Life                         | 30 Days                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 60 Days                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

The new device is similar to the predicate device in that it is drawn into the conductivity meter or the conductivity meter is exposed to the solution. The conductivity meter displays the value it measures for the conductivity.

The new device is different in that there are three additional conductivity values. The new device is using additional two salts (Sodium Bicarbonate and Sodium Sulfate) to the single salt (Sodium Chloride) used in the predicate.

The new device and the predicate provide a secondary standard to be used in verifying or calibrating conductivity cells or instruments. For the purposes of verifying or calibrating Conductivity, the new device is substantially equivalent to the predicate device.

#### Materials Used in the New Device

The following materials are used in the new device. None of these materials contact the patient or any patient fluids.

| <i>Material</i>           | <i>Where used</i> | <i>Common Name</i> | <i>CAS Registry Number</i> | <i>Manufacturer</i>     | <i>Patient or Patient Fluid Contact</i> |
|---------------------------|-------------------|--------------------|----------------------------|-------------------------|-----------------------------------------|
| De-Ionized Water          | Solution          | DI Water           | 7732-18-5                  | Produced in-house       | No                                      |
| Sodium Chloride           | Solution          | NaCl               | 7440-23-5                  | Rocky Mountain Reagents | No                                      |
| Sodium Bicarbonate        | Solution          | Baking Soda        | 144-55-8                   | Rocky Mountain Reagents | No                                      |
| Sodium Sulfate            | Solution          | Thenardite         | 7757-82-6                  | Sigma-Aldrich           | No                                      |
| High-density Polyethylene | Bottle            | HDPE               | 9002-88-4                  | Silgan                  | No                                      |

Comparison of material use between the predicate and the new device.

| <i>Where Used</i>         | <i>Mesa Laboratories, Inc.<br/>Predicate Device 1996<br/>510(k) K955298</i> | <i>Mesa Laboratories, Inc.<br/>New Device 2019<br/>510(k) K191496</i> |
|---------------------------|-----------------------------------------------------------------------------|-----------------------------------------------------------------------|
| De-Ionized Water          | Solution                                                                    | Solution                                                              |
| Sodium Chloride           | Solution                                                                    | Solution                                                              |
| Sodium Bicarbonate        | -                                                                           | Solution                                                              |
| Sodium Sulfate            | -                                                                           | Solution                                                              |
| High-density Polyethylene | Bottle                                                                      | Bottle                                                                |

Validations were performed to demonstrate that the materials performed equivalently for their required function.

#### Performance Testing

The following validations were performed:

##### VP-00020 Conductivity Values of 15ppm TDS Solutions

The purpose of this test was to validate that the value of the new device were correct. A Reference Conductivity meter was used and calibrated using Standard Reference Materials purchased from Cole-Palmer. The TDS value for (5) bottles were: 15.063 ppm, 15.032 ppm, 15.007 ppm, 14.988 ppm and 14.994

ppm. The value of the 15ppm TDS Solution was within the tolerances of the solution and the Reference Conductivity meter. This was considered acceptable as per the Validation Protocol.

#### VP-00021 Conductivity Values of 150ppm TDS Solutions

The purpose of this test was to validate that the value of the new device were correct. A Reference Conductivity meter was used and calibrated using Standard Reference Materials purchased from Cole-Palmer. The TDS value for (5) bottles were: 150.546 ppm, 150.480 ppm, 150.546 ppm, 150.876 ppm and 150.744 ppm. The value of the 150ppm TDS Solution was within the tolerances of the solution and the Reference Conductivity meter. This was considered acceptable as per the Validation Protocol.

#### VP-00022 Conductivity Values of 1500ppm TDS Solutions

The purpose of this test was to validate that the value of the new device were correct. A Reference Conductivity meter was used and calibrated using Standard Reference Materials purchased from Cole-Palmer. The TDS value for (5) bottles were: 1508.18 ppm, 1505.99 ppm, 1505.99 ppm, 1506.72 ppm and 14.994 ppm. The value of the 1500ppm TDS Solution was within the tolerances of the solution and the Reference Conductivity meter. This was considered acceptable as per the Validation Protocol.

#### VP-00030 Open Bottle Shelf Life

The purpose of this test was to validate that the new device would remain within specification for 60 days after the bottle was opened and tightly recapped. The three values 23.8  $\mu\text{S}/\text{cm}$ , 229  $\mu\text{S}/\text{cm}$ , and 2060  $\mu\text{S}/\text{cm}$  were all found to be within tolerance after the bottle was opened for 60 days and then tightly resealed. This was considered acceptable as per the Validation Protocol.

#### VP-00073 Sealed Bottle Storage Shelf Life

The purpose of this test was to validate that the new device would remain within specification for 18 months days after the bottle was sealed. Five different batches of 23.8  $\mu\text{S}/\text{cm}$  were manufactured. The testing consisted of measuring bottles from throughout the bottling run. (5) bottles, one from the 1<sup>st</sup> 20% of the run, one from the 2<sup>nd</sup> 20% of the run, one from the 3<sup>rd</sup> 20% of the run, one from the 4<sup>th</sup> 20% of the run, and one from the last 20% of the run were measured at specified intervals over 18 months. The results showed that the solution remained in tolerance for 18 months. This was used to demonstrate that the batch had uniform properties throughout the production. This was considered acceptable as per the Validation Protocol.

#### VP-00074 Sealed Bottle Storage Shelf Life

The purpose of this test was to validate that the new device would remain within specification for 18 months days after the bottle was sealed. Five different batches of 229  $\mu\text{S}/\text{cm}$  were manufactured. The testing consisted of measuring bottles from throughout the bottling run. (5) bottles, one from the 1<sup>st</sup> 20% of the run, one from the 2<sup>nd</sup> 20% of the run, one from the 3<sup>rd</sup> 20% of the run, one from the 4<sup>th</sup> 20% of the run, and one from the last 20% of the run were measured at specified intervals over 18 months. The results showed that the solution remained in tolerance for 18 months. This was used to demonstrate that the

batch had uniform properties throughout the production. This was considered acceptable as per the Validation Protocol.

#### VP-00075 Sealed Bottle Storage Shelf Life

The purpose of this test was to validate that the new device would remain within specification for 18 months days after the bottle was sealed. Five different batches of 2060  $\mu\text{S}/\text{cm}$  were manufactured. The testing consisted of measuring bottles from throughout the bottling run. (5) bottles, one from the 1<sup>st</sup> 20% of the run, one from the 2<sup>nd</sup> 20% of the run, one from the 3<sup>rd</sup> 20% of the run, one from the 4<sup>th</sup> 20% of the run, and one from the last 20% of the run were measured at specified intervals over 18 months. This was used to demonstrate that the batch had uniform properties throughout the production. The results showed that the solution remained in tolerance for 18 months. This was considered acceptable as per the Validation Protocol.

Additional batches of TDS Solutions were manufactured to demonstrate that the new device would remain within specification during the 18 months in sealed bottle storage. . The goal was to produce the solution with a value within the lower 10% range of the specification range for each TDS solution. This was done to ensure that the value after 18 months of sealed bottle storage remained with specification.

The table below shows the conductivity value of each batch of solution in the mixing tank. The lower specification and the upper specification for each TDS Solution are given in the last two rows of the table.

| TDS Solution        | 15 ppm                              | 150 ppm                             | 1500 ppm                            |
|---------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| Batch               | Tank<br>( $\mu\text{S}/\text{cm}$ ) | Tank<br>( $\mu\text{S}/\text{cm}$ ) | Tank<br>( $\mu\text{S}/\text{cm}$ ) |
| 1                   | 23.56                               | 226.8                               | 2040.0                              |
| 2                   | 23.57                               | 227.3                               | 2040.0                              |
| 3                   | 23.56                               | 226.8                               | 2040.0                              |
| 4                   | 23.57                               | 227.2                               | 2042.0                              |
| 5                   | 23.56                               | 226.9                               | 2042.0                              |
| Lower Specification | 23.324                              | 226.7                               | 2039.4                              |
| Upper Specification | 24.276                              | 231.3                               | 2080.6                              |

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

Conclusions Demonstrating Safety and Effectiveness: The results of the validations show that the new device is equivalent to the Conductivity/TDS Calibrator Solutions. The new device is substantially equivalent to the legally marketed Conductivity/TDS Calibrator Solutions (predicate device).