September 2, 2020

Mesa Laboratories, Inc.
℅ Johannes Pfingstmann
Manager for Quality Assurance & Regulatory Affairs
IBP Medical GmbH
Ikarusallee 15
Hannover, Lower Saxony 30179
Germany

Re: K201765
Trade/Device Name: SmartHDM-510 System
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FIZ
Dated: August 3, 2020
Received: August 3, 2020

Dear Johannes Pfingstmann:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201765

Device Name
SmartHDM-510 System

Indications for Use *(Describe)*
The SmartHDM-510 system may be used by hemodialysis personnel to test the conductivity, temperature, pressure, pH and flow of the dialysate solution used with hemodialysis delivering systems.

The SmartHDM-510 system may also be used to test the conductivity/temperature and pH of acid and sodium bicarbonate dialysate concentrates and water used in hemodialysis applications.

The intended use is limited to periodic use for installation and maintenance of hemodialysis delivering systems and does not include the daily monitoring of hemodialysis delivering systems prior to treatment.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter Mesa Laboratories, Inc.
Address 12100 West 6th Avenue
Lakewood, CO 80228
Internet www.mesalabs.com

Contact Person Johannes Pfingstmann
eMail johannes.pfingstmann@ibpmt.com
Phone number +49 511 957 336 0

Date preparation June 24**,** 2020

Name of the device SmartHDM-510 System

Common Name Hemodialysis Service System

Classification

Classification Name:	Hemodialysis System and Accessories
Product Code:	FIZ
Device Class:	2
Regulation Number:	21 CFR 876.5540
Medical Specialty:	Gastroenterology

Predicate Devices

K020909 HDM99 (Dialysis Meters) primary device
K020908 HDM97 (Dialysis Meters)
K050812 90XL Instrumentation System

Devices Description

The SmartHDM-510 System is designed for the installation and maintenance of hemodialysis delivering systems. The system consists of different sensors and sensor-modules to measure conductivity, temperature, pressure, pH and flow and an Android operating system based display module with SmartHDM-510 App.

SmartHDM-510 System 510(k) Summary

The SmartHDM-510 system consists of:

- HDU-Sensors for Conductivity/Temperature, Pressure, pH and flow
- HDM-Sensor Modules for Conductivity/Temperature, Pressure,
- 90XL-Sensors for Conductivity/Temperature, Pressure and pH
- Android-based Display Module with SmartHDM-510 App.

Indication for Use

The SmartHDM-510 system may be used by hemodialysis personnel to test the conductivity, temperature, pressure, pH and flow of the dialysate solution used with hemodialysis delivering systems.

The SmartHDM-510 system may also be used to test the conductivity/temperature and pH of acid and sodium bicarbonate dialysate concentrates and water used in hemodialysis applications.

The intended use is limited to periodic use for installation and maintenance of hemodialysis delivering systems and does not include the daily monitoring of hemodialysis delivering systems prior to treatment.

Comparative Analysis

In comparison to the predicate device, the SmartHDM-510 System has a high-resolution screen.

Based on the high-resolution screen, the clear display of the measurement conditions makes the reading of the measured values more reliable. The improved graphical display of the measured values makes errors on the device to be serviced more visible. Information texts and messages make the operation safer.

Listed below are the major attributes of the SmartHDM-510 System compared to the predicate devices listed:

SmartHDM-510 System 510(k) Summary

Specification	Predicate Device 1	Predicate Device 2	Predicate Device 3	New Device
	HDM99 (Primary)	HDM97	90XL	SmartHDM-510 System
General				
510(k) Number	K020909	K020908	K050812	
Design	Handheld device with connectors for internal and external sensors		Handheld display unit with connectors for external sensors	
Display – General functions				
Operating System	R-THOS	None	None	Android
Automated security patches	N/A	N/A	N/A	Yes
Battery status reading	Yes	Yes	Yes	Yes
Display size	37 x 137 mm 1.46 x 5.39 “	55 x 43 mm 2.16 x 1.69 “	57 x 76 mm 2.24 x 2.99 “	HDC64 5.7” HDC85 8”
Color Display	No	No	No	Yes
Hint Texts	No	No	No	Yes
Display selection of connected sensors	Yes	Yes	No	Yes
Display single value	Yes	Yes	Yes	Yes
Display single value including graphic	Yes	No	No	Yes
Display several values as list	Yes	No	Yes	Yes
Display graphic reading as list	No	No	No	Yes
Selection of time range for graphic display	Yes	No	No	Yes
Selection of y- range for graphic display	Yes	No	No	Yes
Statistic values	No	No	No	Yes
User hints	No	No	No	Yes

SmartHDM-510 System 510(k) Summary

Display - measuring functions				
	HDM99 (Primary)	HDM97	90XL	SmartHDM-510 System
Conductivity adjustment	Yes	Yes	Yes	Yes
Conductivity adjustment reset	Yes	Yes	No	Yes
Selection Conductivity/ Temperature Compensation by vendor name	Yes	Yes	No	Yes
Conductivity resolution selection	Yes	No	No	Yes
Pressure unit selection	Yes	Yes	Yes	Yes
Pressure resolution selection	Yes	Yes	No	Yes
Pressure Tare function	Yes	Yes	Yes	Yes
Pressure change measurement	No	Yes	No	Yes
pH adjustment	Yes	Yes	Yes	Yes
pH adjustment points	3	3	2	3
pH temperature compensation selection	Yes	Yes	No	Yes
Flow accumulation display	Yes	Yes	Not Applicable	Yes
Flow accumulation reset	Yes	Yes	Not Applicable	Yes
HDU-Sensors and HDM18/19 Modules				
	HDM99	HDM97 and HDM18/19	90XL	HDU-Sensor
Conductivity/Temperature measuring via Dialyzer Connector	Yes	Yes	Yes	Yes
Conductivity Measuring Range	0 to 24 mS/cm	0 to 30 mS/cm	0 to 200 mS/cm	0 to 200 mS/cm
Conductivity Range Accuracy	0 to 249.9 uS/cm ± 0.6 uS/cm	0 to 199 uS/cm ± 0.6 uS/cm	0 to 1.99 mS ±0.35% of reading + 0.002 mS/cm	0 to 199.9 uS/cm ± 0.6 uS/cm
	250 to 2499 uS/cm ± 6 uS/cm	200 to 1999 uS/cm ± 6 uS/cm	2 to 29.99 mS/cm ± 0.20% of reading + 0.002,	200 to 1999 uS/cm ± 6 uS/cm
	2.5 to 16.99 mS/cm ± 0.06 mS/cm	2 to 11.99 mS/cm ± 0.06 mS/cm	> 30 mS/cm ± 0.50% of reading	2 to 11.99 mS/cm ± 0.06 mS/cm
	17 to 24 mS/cm ± 0.06 mS/cm	12 to 15.99 mS/cm ± 0.03 mS/cm		12 to 19.99 mS/cm ± 0.03 mS/cm
		16 to 30 mS/cm ± 0.06 mS/cm		20 to 200 mS/cm ± 0.60% of reading

SmartHDM-510 System 510(k) Summary

Remark to measuring ranges	The important range for hemodialysis is 14 to 16 mS/cm. The measuring range of predicate HDM97 and HDM18/19 are identical. The measuring range of predicate 90XL- and HDU-Conductivity/Temperature sensors are identical.			
Temperature Measuring Range	0 to 100 °C	0 to 100 °C	10 to 90°C	0 to 100 °C
Temperature Accuracy	± 0,1 °C	± 0.1°C	± 0.1°C	± 0.1°C
Pressure Measuring Range	-700 to +1500 mmHg	-700 to + 1900 mmHg	-600 to +1600 mmHg	-672 to +1551 mmHg
Pressure Accuracy	-700 to +1500 mmHg ± 0.5% of reading	HDM97 0 to 300 mmHg ± 1 mmHg otherwise ± 2 mmHg HDM18/19 Internal ± 2 mmHg External 0 to 300 mmHg ± 1 mmHg otherwise ± 2 mmHg	0 to 199 mmHg ±1.0 mmHg, 200 to 300 mmHg ± 1.5 mmHg above 300 mmHg and below 0 mmHg ± 0.5% of reading + 1 mmHg	0 to 300 mmHg ± 1 mmHg otherwise ± 2 mmHg
Flow Measuring Range	100 to 2000 ml/min	100 to 2000 ml/min	Not Applicable	100 to 2000 ml/min
Flow Measuring Accuracy	100 to 2000 ml/min ± 0.5 % full scale	± 2.0 % of reading	Not Applicable	± 2.0 % of reading
pH Measuring Range	0...14 pH	0...14 pH	0...14 pH	0...14 pH
pH Measuring	± 0.02 pH	± 0.02 pH	± 0.1 pH	± 0.02 pH
Communication Interface				
USB	Yes	Yes	No	Yes
Bluetooth	No	Only HDM19	No	No
WIFI	No	No	No	Yes
Remark to WIFI	SmartHDM-510 uses WIFI / Internet connections by HTTPS protocol, TCP port 443. These connections are for displaying manuals, or a registration page for a user or legal information which are not stored in the App itself. The servers of Mesa Laboratories offer TLS1.2, TLS1.1, TLS1.0 as the encryption method. WIFI is not used for measuring purposes or other SmartHDM-510 use cases at all.			
Cybersecurity	Not applicable	Not applicable	Not applicable	Applicable
Remark to Cybersecurity	• SmartHDM-510 has no open incoming network ports • SmartHDM-510 interacts only with HTTPS secured Mesa Laboratories websites on user action (outgoing connection) such as Mesa Laboratories WEB pages and Mesa Laboratories PDF's for: User manuals and legal information. • SmartHDM-510 is updated by Google Play Store functionalities only • SmartHDM-510-App is signed by Mesa Laboratories development and Google and only spread by Google Play Store • Bluetooth (LE) is only used for a special purpose and is not open to other devices except these of Mesa Laboratories			

Performance Testing

The performance testing for the SmartHDM-510 System includes software testing and code reviews, system verification and validation testing, and testing to compliance standards for electrical and electromagnetic safety. Traceability has been documented between the system specification to verification and validation test protocols. Verification and validation test procedures also address the user interface, user manual descriptions, usability, sensor communication and general performance including measuring accuracy.

The design of the device has been verified and validated both through testing and actual experience in international use.

The testing and international experience provided data that demonstrated substantial equivalence to the predicate devices.

Conclusion

The characteristics of the SmartHDM-510 System are identical to those of the predicate devices in almost all categories. The device has the same intended use as its primary predicate device. Also, it has similar measuring ranges and measuring accuracy as the predicate.

Different to HDM99 and the HDM97, where the display unit, all measuring electronic and pressure sensor are integrated into one housing, and identical to the 90XL, the SmartHDM-510 System consist of separate devices for the display unit and external connected sensors with integrated measuring electronic. However, SmartHDM-510 System passed all performance tests and hence is as safe as its predicate devices.

The performance of the SmartHDM-510 System is substantially equivalent to that of the predicate devices and do not raise any new questions of safety or effectiveness and performs as well or better than the predicate devices.

Therefore, we conclude that it is substantially equivalent to its cleared predicate devices.