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

March 30, 2017

HACH Company
Jeff Ryberg
Vice President RA /QA
100 Dayton Avenue
Ames, IA 50010

Re: K162471
Trade/Device Name: CM130 Chlorine Monitor
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water Purification System For Hemodialysis
Regulatory Class: II
Product Code: PSX, FIP
Dated: February 24, 2017
Received: February 27, 2017

Dear Jeff Ryberg:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Joyce M. Whang -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162471

Device Name
CM130 Chlorine Monitor

Indications for Use *(Describe)*
The Hach CM130 is an instrument that is intended for use by hemodialysis professionals to automatically monitor low levels of total chlorine (i.e. total chloramines plus free chlorine) in feed water used to prepare dialysate in hemodialysis systems.

The CM130 is a component of the complete water treatment system for hemodialysis and does not treat or alter the water used in dialysate. The CM130 instrument's automated monitoring records total chlorine values in feed water at intervals between 5 and 20 minutes.

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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Section 6: 510 (k) SUMMARY

1. Submitted by:

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Contact: **Jeff Ryberg, VP RA/QA**

2. Date Prepared: March 30, 2017

3. Device Name: Water Purification System for Hemodialysis Auxiliary Component

Classification of Device: Class II
21 CFR 876.5665
Primary Product Code PSX
Secondary Product Code FIP

4. Trade Name of Proposed Device: Hach CM130 Chlorine Monitor

6. Predicate Device:

Sub-System	Predicate Device Name	Description	510(k) Number
Chemistry	SteriChek® Total Chlorine DPD Kit	Chlorine Measurements	K983997

7. Reference Devices:

Sub-System	Reference Device Name	Description	510(k) Number
Water Sample Conditioning and Delivery	Gambro Central Water Treatment System, CWP 100 WRO H	Water Flow Control	K974899
Reagent Delivery	AP 34 Multi-Therapy Infusion Pump	Fluid movement using a Peristaltic pump	K082182

Sub-System	Reference Device Name	Description	510(k) Number
Measurement Chamber	DensiChek Plus Fully Automated Short Term Incubation Cycle Antimicrobial Susceptibility Device	Provides measurements based on the optical density of a microorganism suspension	K093244
Electronic Hardware Software Controls with Enclosure	Dialysate Meter, Model D-6	Microprocessor controlled automation in a water room	K100237
Remote Indicator	AmeriWater Alarm	Remotely mounted device "state" indicator	K121022

8. Proposed Device Description:

The Hach CM130 Chlorine Monitor is a microprocessor-controlled analyzer used to monitor the chlorine content of water which is used to prepare dialysate for hemodialysis. The monitor is mounted in the water room in a location that allows sampling of feed water between the primary (scrubbing) and secondary (polishing) carbon tanks. Water that flows into the CM130 exits the device to a drain. The water samples, once tested, are also discarded to a drain.

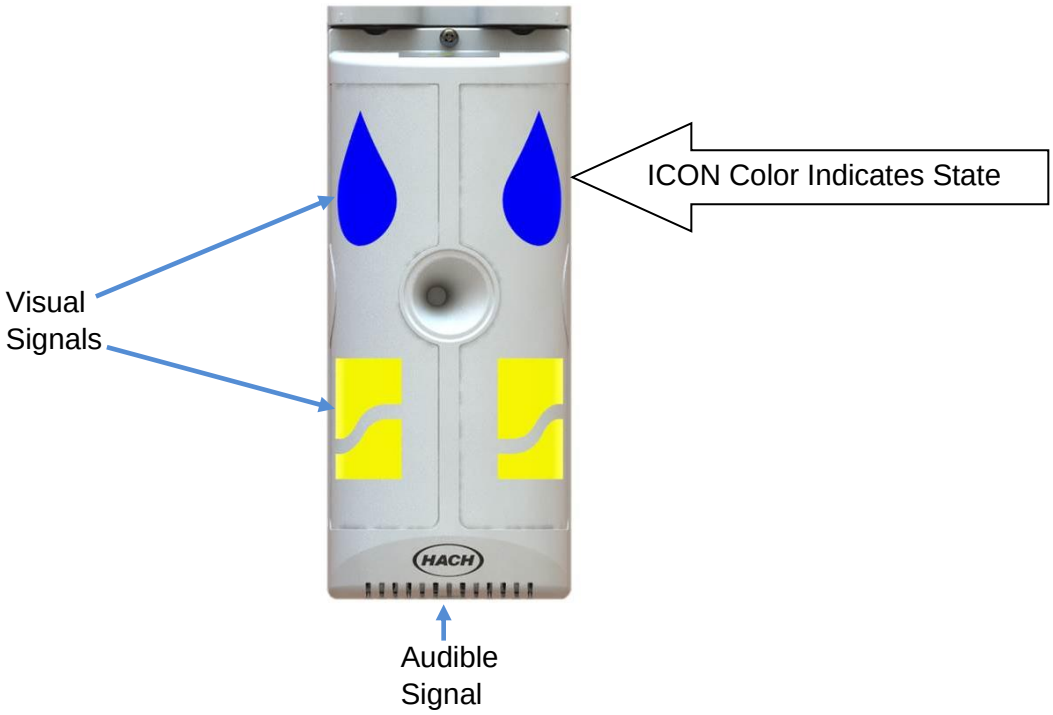
The monitor measures and displays total chlorine (free chlorine and combined chloramines) as Cl_2, ranging from 0.03 to 0.20 mg/L.

Section 6 – Figure 1: CM130 Chlorine Monitor

CM130 Chlorine Monitor 510 (k)
March 30, 2017 **510 (k) SUMMARY**

The CM130 Chlorine Monitor employs a DPD Colorimetric Method for the detection of total chlorine. The analyzer introduces N,N-Diethyl-p-phenylenediamine (DPD) indicator with potassium iodide and a buffer to the water sample under test. The indicator and buffer are allowed to react with the chlorine and chloramines present in the water. The reaction results in a dye which forms a red color in the water sample. The intensity of the red color is proportional to the total chlorine concentration. It is measured photometrically and the results are automatically recorded and displayed.

The Remote Indicator (RI) is a subsystem that is mounted in the patient treatment area, typically near the ceiling, so that it can be easily seen. Its primary function is to communicate the status of the chlorine concentration of the feed water and the status of the analyzer to the staff while they are working in the patient treatment room.



Section 6: Figure 2:
CM130's Remote Indicator (RI)

The CM130 Chlorine Monitor and the Remote Indicator will each provide both an audible and a visual signal.

Alert

An alert is a signal to inform staff that total chlorine measurements indicate concentrations have increased (medium – high), but are still acceptable. This predefined "alert" level is greater than .07 mg/L but less than 0.1 mg/L Cl_2. Notification at this point with an amber illumination and alert tone, allows staff to address maintenance of the water system at a time that is relatively convenient.

Alarm

The analyzer and the Remote Indicator each provide both an audible and a visual "Alarm" signal when the total Chlorine exceeds the standard allowable level of 0.1 mg/L Cl_2.

9. Indications for Use:

The Hach CM130 is an instrument that is intended for use by hemodialysis professionals to automatically monitor low levels of total chlorine (i.e. total chloramines plus free chlorine) in feed water used to prepare dialysate in hemodialysis systems.

The CM130 is a component of the complete water treatment system for hemodialysis and does not treat or alter the water used in dialysate. The CM130 instrument's automated monitoring records total chlorine values in feed water at intervals between 5 and 20 minutes.

10. Summary of Technological Characteristics of New Device Compared to Predicate and Reference Devices

The proposed CM130 Chlorine Monitor uses the same chlorine detection technology (DPD color reaction) as the predicate. Both products are used to monitor feed water used to prepare dialysate.

However, providing automatic measurements, the CM130 Chlorine Monitor adds technological features not found in the predicate device. These technological features include:

1. Automated water sample conditioning and delivery
2. Automated reagent delivery
3. Automated measurements
4. Electronic hardware and software used to control device operation
5. A Remote Indicator (RI) to allow individuals in the patient treatment area, to monitor the status of equipment in the water room
6. An Enclosure to protect electronics from incidental splashing or spills

11. Summary of Performance Testing Supporting Substantial Equivalence

System Performance Testing

Non-clinical testing was conducted on the CM130 Chlorine Monitor. Performance verification and validation testing demonstrate that the CM-130 Chlorine Monitor system and subsystems are safe and effective for their intended use.

Description	Performance Test Comment
CM130 Bias Verification	Demonstrates the ability of the CM130 to match a known reference reading (Accuracy) and compares performance to the Predicate Devices ability to match a known reading.
CM130 Repeatability - Reproducibility Verification	Demonstrates within instrument and between instrument variations.
CM130 Reproducibility of the Predicate	Comparative reproducibility demonstrates there is less variation with the CM130
Effects of Iron Cations on Total Chlorine Measurements Note: Minerals are grouped see intro to each protocol	Interference Testing Interferences are tested to limits allowed in water by standards. The testing demonstrates the device performs acceptably even when potentially "interfering" chemicals are present. The results are published in the instructions for use
Effects of Metal Cations on Total Chlorine Measurements	
Effects of Additional Inorganics on Total Chlorine Measurements	

Performance testing was conducted on the CM130 Chlorine Monitor and on the predicate device using the same solutions and test setups with modifications as appropriate for the differences between manual and automated testing. The CM130 Chlorine Monitor is designed to test automatically, generating a measurement of a new sample of water every 5 minutes during use. The predicate is a manual process that takes an unspecified amount of time to collect and process each water sample.

The devices have similar measurement capability in that the predicate scale is manually read to the nearest .02 mg/L and is interpolated to .01 mg/L while the CM130 Chlorine Monitor measures to .01mg/L Cl2.

Accuracy (Bias) and Precision (Repeatability) verifications were conducted under CLSI-EP Standards. These protocols address equivalency testing with the CM130 Chlorine Monitor results compared to the predicate.

Bias testing covered the entire measurement range of the CM130 Chlorine Monitor. Test measurements for each device are compared to a reference method used to independently verify the "true" measurement.

Electrical Safety Testing
The CM-130 Chlorine Monitor has been evaluated against the requirements for electromagnetic compatibility and electrical safety in accordance with IEC61326-1 and IEC61010-1.

Software Verification and Validation Testing
The CM-130 Chlorine Monitor software was developed, verified and validated in accordance with the applicable FDA guidance documents. The results of the verification and validation activities demonstrate the software performs as intended.

Alarm Testing
The CM130 system was tested for alarm performance following CLSI EP12-A2. The positive and negative alarm performance demonstrate the device is safe and effective for intended use.

Reagent Shelf Life and Use Life Testing
The CM130 reagents were tested to confirm that they met the specified shelf life and use life. The reagents meet all specifications when stored upright in the marketing container at the specified temperatures. The results of the shelf life and use life testing demonstrate the device is safe and effective for intended use.

Human Factors Testing
The CM130 was tested for human factors usability per ANSI/AAMI HE75:2009. The CM130 has been found to be safe and effective for the intended users, uses and use environments as demonstrated in summative simulated and actual use testing of the user interfaces with representative users. The Human Factors Engineering and Usability Engineering process involved several methodologies, including observational user research, formative user testing and summative user testing. Formative and summative user testing included simulated use and actual use tasks for both user groups. Based on subjective and objective data it can be concluded that all users can safely and effectively use the device.

12. Conclusion
CM-130 Chlorine Monitor non-clinical performance, electrical safety, software verification and validation, alarm testing, reagent and use life testing and

human factors testing demonstrate the device is safe and effective for its intended use.

The proposed device uses the same active chemistry, has the same intended use, and has labeling similar to the predicate device. The CM130 Chlorine Monitor is also similar to the reference devices in specific technological features.

The predicate and subject devices were tested to plan with passing results, therefore demonstrating substantial equivalence.