



October 29, 2020

Nelson Environmental Technologies, Inc.
QuocHuy (Huy) Nguyen
New Product Development Manager/Finance Manager
813 E. Fir Avenue
McAllen, TX 78501

Re: K193169
Trade/Device Name: Nelson Sentinel Series Basic Chlorine Sentinel
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water Purification System for Hemodialysis
Regulatory Class: II
Product Code: PSX, MSY, FIP
Dated: September 28, 2020
Received: September 29, 2020

Dear QuocHuy (Huy) Nguyen:

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,

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

Indications for Use

510(k) Number (if known)
K193169

Device Name
Nelson Sentinel Series Basic Chlorine Sentinel

Indications for Use (Describe)

The Nelson Sentinel Series Basic Chlorine Sentinel is an instrument that is intended for use by hemodialysis professionals as an auxiliary device to provide continuous monitoring of Total Chlorine. (i.e. total chloramines plus ammoniated free chlorine) concentration. It is not intended to replace the primary method for monitoring total chlorine as part of the hemodialysis water treatment system. It functions completely independent of the water treatment system and does not come into direct contact with feed water used to prepare dialysate.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

6. 510(k) Summary

Nelson Environmental Technologies, Inc.

This 510(k) Summary is in conformance with 21CFR 807.92

Submitter: Nelson Environmental Technologies, Inc.
813 E. Fir Avenue
McAllen, TX 78501
Phone: 956-618-0375

Primary Contact: QuocHuy (Huy) Nguyen
Email: admin@nws.bz
Phone: 956-618-0375
Fax: 956-618-4330

Date Prepared: August 13, 2020

Device Name and Classification

Trade Name/Device Name: Nelson Sentinel Series Basic Chlorine Sentinel
Regulation Number: 21 CFR 876.5665
Regulation Name: Water Purification System for Hemodialysis
Regulatory Class: Class II
Classification Panel: Gastroenterology/Urology
Product Code: PSX, MSY, FIP

Predicate Device:

Trade Name	Ultra Low Total Chlorine (K100-0118) and E-Z Chek Sensitive Total Chlorine (K100-0106) Test Strips
Common Name	Total Chlorine Test Strips
510(k) Submitter / Holder	Reprocessing Products Corporation (RPC)
510(k) Number	K090338
Regulation Number	21 CFR§ 876.5665 Water purification system for hemodialysis
Classification Panel	Gastroenterology/Urology
Product Code	MSY

Reference Device:

Trade Name	Hach CM130 Chlorine Monitor
Common Name	
510(k) Submitter / Holder	HACH Company
510(k) Number	K162471
Regulation Number	21 CFR§ 876.5665 Water Purification System For Hemodialysis
Classification Panel	Gastroenterology/Urology
Product Code	Primary Product Code PSX Secondary Product Code FIP

Device Description

The Nelson Sentinel Series Basic Chlorine Sentinel is a complete system that attaches to the drain of a hemodialysis water treatment system sample port. The Basic Chlorine Sentinel detects dissolved chlorine by an auxiliary meter detection technology, self-monitors for maintenance-required conditions, loss of electrical power, as well as two other system conditions such as flooding and the status of RO shutdown alarm. The device chlorine monitoring probe is preferably placed after the second carbon filter, before the RO machine or at the beginning of the patient water treatment loop.

The device has three components – a lockable master control enclosure, a lockable probe/tester enclosure, and the remote module installed in the patient area.

A chlorine concentration equal to or above the set-point (default: 0.10mg/L) will activate the buzzers and the red **CHLORINE** alarm indicators for as long as the condition exists. The buzzers can only be muted for 3 minutes (then automatically reset) for as long as the condition exists. The yellow **AUTO-TEST OK/CL DETECTED** indication will latch. The **AUTO-TEST/CL DETECTED** indication can be deactivated after the event by pressing the blue **RESET PUSHBUTTON** on the front cover of the controller.

A probe failure or the activation of one of the auxiliary input relays will activate the yellow **MAINTENANCE** needed indicators as well as the **Buzzers** which will remain activated as long as the condition exists. However, the buzzers can be muted by the key mute switch while the maintenance issue is being resolved.

Indications for Use

The Nelson Sentinel Series Basic Chlorine Sentinel is an instrument that is intended for use by hemodialysis professionals as an auxiliary device to provide continuous monitoring of Total Chlorine. (i.e. total chloramines plus ammoniated free chlorine) concentration. It is not intended to replace the primary method for monitoring total chlorine as part of the hemodialysis water

treatment system. It functions completely independent of the water treatment system and does not come into direct contact with feed water used to prepare dialysate.

Risk Analysis Method

Nelson Sentinel Series Basic Chlorine Sentinel was assessed to determine risks to health associated with the use of the device, a risk analysis was conducted in accordance with ISO 14971: 2007, Medical devices – Application of risk management to medical devices.

Substantial Equivalence

The table below provides a detailed comparison of Nelson Sentinel Series Basic Chlorine Sentinel to the predicate and reference devices.

Detailed Comparison of the Subject and Predicate Devices

Item	Subject Device Nelson Sentinel Series Basic Chlorine Sentinel	Predicate Device UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips	Reference Device Hach CM130 Chlorine Monitor	Comparison
Intended Use/Indications for Use	The Nelson Sentinel Series Basic Chlorine Sentinel is an instrument that is intended for use by hemodialysis professionals as an auxiliary device to provide continuous monitoring of Total Chlorine. (i.e. total chloramines plus ammoniated free chlorine) concentration. It is not intended to replace the primary method for monitoring total chlorine as part of the hemodialysis water treatment system. It functions completely independent of the water treatment system and does not come into direct contact with feed water used to prepare dialysate.	The Reprocessing Product Corporation (RPC) Total Chlorine Test Strips are indicated for detection of Free Chlorine and Total Chlorine in water. These Test Strips are indicated for testing water used to prepare dialysate (Free Chlorine and Chloramines) and for testing rinse water following dialysis equipment disinfection (Free Chlorine).	N/A; Nelson Sentinel Series Basic Chlorine Sentinel is compared to UltraLow Total Chlorine and E-Z Chk Sensitive Total Chlorine Test Strips for Intended Use and Indications For Use.	The Nelson Sentinel Series Basic Chlorine Sentinel intended use / indications for use is identical to the UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips intended use and indications for use, related to the detection of Total Chlorine in Water and testing water used to prepare dialysate.

Item	Subject Device Nelson Sentinel Series Basic Chlorine Sentinel	Predicate Device UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips	Reference Device Hach CM130 Chlorine Monitor	Comparison
Provides Exact Chlorine Value?	No; Intended to indicate chlorine above set-point only	No; Indicates an approximate, semi-quantitative value based on the colorimetric method, which can be used to confirm if chlorine is above a specific value	Yes; presents an exact chlorine value on its display intended to be used to make clinical decisions	Nelson Sentinel Series Basic Chlorine Sentinel is equivalent to UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips.
Detection Chemistry/ Technology	Direct measuring polarographic sensor utilizing a special polymeric membrane.	N/A	DPD Colorimetric Method	Nelson Sentinel Series Basic Chlorine Sentinel uses a different detection technology from Hach CM130 Chlorine Monitor. The difference in detection technology does not affect the intended use or the safety of the device.
Chlorine Sensor Type	Polarographic sensor	N/A	Photometric sensor	Nelson Sentinel Series Basic Chlorine Sentinel uses a different sensor from Hach CM130 Chlorine Monitor. The difference in sensor type does not affect the intended use or the safety of the device.

Item	Subject Device Nelson Sentinel Series Basic Chlorine Sentinel	Predicate Device UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips	Reference Device Hach CM130 Chlorine Monitor	Comparison
Reagents	Ammonium sulfate	N/A	Indicator solution (DPD indicator with potassium iodide), buffer solution	<p>The reagents used by Nelson Sentinel Series Basic Chlorine Sentinel and Hach CM130 Chlorine Monitor are different.</p> <p>The difference in reagents used does not affect the intended use or safety and effectiveness of the device.</p>
Reagent Delivery	Peristaltic pump	N/A	Peristaltic pump	Nelson Sentinel Series Basic Chlorine Sentinel is identical to Hach CM130 Chlorine Monitor.
Type of Chlorine Detected	Total Chlorine (free chlorine plus total chloramines)	N/A	Total Chlorine (free chlorine plus total chloramines)	Nelson Sentinel Series Basic Chlorine Sentinel is identical to Hach CM130 Chlorine Monitor.

Item	Subject Device Nelson Sentinel Series Basic Chlorine Sentinel	Predicate Device UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips	Reference Device Hach CM130 Chlorine Monitor	Comparison
Detection Range	0.05 mg/L Cl ₂ – 0.15 mg/L Cl ₂	N/A	0.03 mg/L Cl ₂ – 0.20 mg/L Cl ₂	Nelson Sentinel Series Basic Chlorine Sentinel is able to detect a wider range of chlorine levels than Hach CM130 Chlorine Monitor. This difference in detection range does not affect the intended use or safety and effectiveness of the device.
Allowable Chlorine Level	0.1 mg/L Cl ₂	N/A	0.1 mg/L Cl ₂	Nelson Sentinel Series Basic Chlorine Sentinel is identical to Hach CM130 Chlorine Monitor.
Sampling	The chlorine sensor is located on the downstream side of a water treatment test sample port. The sampled water is then discharged down the drain.	N/A	Feed water is sampled. Water that flows into the CM130 device exits the device to a drain. The water samples, once tested, are also discarded to a drain.	Nelson Sentinel Series Basic Chlorine Sentinel is equivalent to Hach CM130 Chlorine Monitor.
Water Sample Conditioning and Delivery	Automated	N/A	Automated	Nelson Sentinel Series Basic Chlorine Sentinel is identical to Hach CM130 Chlorine Monitor.

Item	Subject Device Nelson Sentinel Series Basic Chlorine Sentinel	Predicate Device UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips	Reference Device Hach CM130 Chlorine Monitor	Comparison
Measurement Interval	Continuous	N/A	5 minutes	<p>Nelson Sentinel Series Basic Chlorine Sentinel has a higher measurement interval than Hach CM130 Chlorine Monitor.</p> <p>This difference in measurement interval does not affect the safety or effectiveness of the device.</p>
Alarms/ Alerts	<p>Controller: Three colors (green for power indication, and yellow and red for alerts) and a buzzer</p> <p>Remote Module: Three colors (green for power indication, yellow and red for alerts) and a buzzer</p>	N/A	<p>Analyzer: Two colors (amber and red) on the display and three sounds for notifications.</p> <p>Remote Indicator: Two lights show the analyzer status (blue, amber, or red). Two lights show the chlorine status (blue, amber, or red). Three different sounds: hardware alarm, medium-high chlorine alert, and high chlorine alarm.</p>	<p>Nelson Sentinel Series Basic Chlorine Sentinel is equivalent to Hach CM130 Chlorine Monitor.</p> <p>Differences in light colors and types of sounds do not affect the intended use or safety and effectiveness of the device.</p>

Item	Subject Device Nelson Sentinel Series Basic Chlorine Sentinel	Predicate Device UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips	Reference Device Hach CM130 Chlorine Monitor	Comparison
Measurement Point	After the secondary carbon filter, before the reverse osmosis (RO) machine.	N/A	Between the primary and secondary carbon tanks (filters).	Nelson Sentinel Series Basic Chlorine Sentinel is different from Hach CM130 Chlorine Monitor. This difference in measurement point does not affect the intended use or the safety and effectiveness of the device.
Device Location	Remote Module is located in the nurse's station; all other components are located in the water room	N/A	Remote indicator is located in the patient room; all other components are located in the water room	Nelson Sentinel Series Basic Chlorine Sentinel is equivalent to Hach CM130 Chlorine Monitor.
Remote Indicator	Yes	N/A	Yes	Nelson Sentinel Series Basic Chlorine Sentinel is identical to Hach CM130 Chlorine Monitor.
Enclosure to protect electronics from splashing or spills	Yes	N/A	Yes	Nelson Sentinel Series Basic Chlorine Sentinel is identical to Hach CM130 Chlorine Monitor.

Item	Subject Device Nelson Sentinel Series Basic Chlorine Sentinel	Predicate Device UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips	Reference Device Hach CM130 Chlorine Monitor	Comparison
Water Treatment?	No	N/A	No	Nelson Sentinel Series Basic Chlorine Sentinel is identical to Hach CM130 Chlorine Monitor.
Device Components	Controller, Probe/Tester, Remote Module	N/A	Analyzer, Remote Indicator	Nelson Sentinel Series Basic Chlorine Sentinel is equivalent to Hach CM130 Chlorine Monitor. This difference in device components does not affect the intended use or safety and effectiveness of the device.
Control Mechanism	Microcontroller	N/A	Microcontroller	Nelson Sentinel Series Basic Chlorine Sentinel is identical to Hach CM130 Chlorine Monitor.
Maintenance	Quarterly	N/A	Monthly	Nelson Sentinel Series Basic Chlorine Sentinel requires less frequent maintenance than Hach CM 130 Chlorine Monitor. The difference in maintenance interval does not affect the intended use or safety and effectiveness of the device.

Item	Subject Device Nelson Sentinel Series Basic Chlorine Sentinel	Predicate Device UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips	Reference Device Hach CM130 Chlorine Monitor	Comparison
Data Logger	No data logger.	N/A	3000 measurements maximum	Data logging features are not available for Nelson Sentinel Series Basic Chlorine Sentinel. This difference does not affect the intended use or safety and effectiveness of the device.
Status Outputs	Five water treatment status outputs: (1) Continuous auxiliary monitoring of Total Chlorine (i.e. total chloramines plus ammoniated free chlorine) concentration (this is not to be confused with primary or secondary testing for chlorine. The device display is for calibration function only and is not to be used for accurate chlorine concentration readings. The device	N/A	High chlorine	Nelson Sentinel Series Basic Chlorine Sentinel provides additional status outputs from the Hach CM130 Chlorine Monitor. This difference does not affect the intended use or safety and effectiveness of the device.

Item	Subject Device Nelson Sentinel Series Basic Chlorine Sentinel	Predicate Device UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips	Reference Device Hach CM130 Chlorine Monitor	Comparison
	<p>does not record usable chlorine concentration values, it only compares the actual concentration to the set-point). When the concentration equals or exceeds the pre-set set-point, the notification output is activated. Notification closes Output Relay #1;</p> <p>(2) Loss of system or facility mains electrical power. Default Output Relay #2;</p> <p>(3) Aux#1 Input (recommended for the status of flood detection monitors), (it does not control any equipment). Notification closes Output Relay #3;</p> <p>(4) Aux #2 Input (recommended for the</p>			

Item	Subject Device Nelson Sentinel Series Basic Chlorine Sentinel	Predicate Device UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips	Reference Device Hach CM130 Chlorine Monitor	Comparison
	status of flood detection monitors), (it does not control any equipment) Notification closes Output Relay #4 (5) Self-diagnostic system failures or maintenance required.			
Display	Backlit LCD: 1.91 cm (0.75 in.)high 4-digit main display, 0.76 cm (0.3 in.) 5x7 dot matrix 12-digit secondary display	N/A	10.9 cm (4.3 in.) color display, backlit LCD< WQVGA	Nelson Sentinel Series Basic Chlorine Sentinel is equivalent to Hach CM130 Chlorine Monitor, with the only difference being that Nelson Sentinel Series Basic Chlorine has a smaller screen than Hach CM130 Chlorine Monitor. This difference in screen size does not affect safety or effectiveness of the device.
Power Requirement	110 – 240 VAC line power	N/A	100 – 240 VAC, 50/60 Hz, 1 A max	Nelson Sentinel Series Basic Chlorine Sentinel is equivalent to Hach CM130 Chlorine Monitor.

Item	Subject Device Nelson Sentinel Series Basic Chlorine Sentinel	Predicate Device UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips	Reference Device Hach CM130 Chlorine Monitor	Comparison
Dimensions	<p>Controller: 38.0 x 46.0 x 16.5 cm (15 x 18 x 6.5 in.)</p> <p>Probe/Tester: 22.5 x 31.0 x 18.5 cm (8.875 x 12.125 x 7.5 in.)</p> <p>Remote Module: 20.0 x 14.5 x 10.0 cm (4.5 x 6.5 x 1.75 in.)</p>	N/A	<p>Analyzer: 37.0 x 53.8 x 22.6 cm (14.6 x 21.2 x 8.9 in.)</p> <p>Remote indicator: 12.3 x 19.4 x 10.7 cm (4.8 x 11.6 x 4.2 in.)</p>	<p>The dimensions of Nelson Sentinel Series Basic Chlorine Sentinel components are different from the dimensions of Hach CM130 Chlorine Monitor components.</p> <p>This difference in dimensions does not affect the intended use or safety and effectiveness of the device.</p>
Weight	<p>Controller: 6.5 kg (14.3 lbs.)</p> <p>Probe/Tester: 3 kg (6.6 lbs.)</p> <p>Remote Module: 0.25 kg (0.5 lbs.)</p>	N/A	<p>Analyzer: 8.9 kg (19.6 lbs.)</p> <p>Remote Indicator: 1.1 kg (2.5 lbs.)</p>	<p>The weights of the Nelson Sentinel Series Basic Chlorine Sentinel components are different from the weights of the Hach CM130 Chlorine Monitor components.</p> <p>This weight difference does not affect the intended use or safety and effectiveness of the device.</p>

Item	Subject Device Nelson Sentinel Series Basic Chlorine Sentinel	Predicate Device UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips	Reference Device Hach CM130 Chlorine Monitor	Comparison
Materials	Controller: PVC and stainless steel monitor, ABS plastic enclosure Probe/Tester: ABS plastic enclosure Remote Module: ABS plastic enclosure	N/A	Analyzer: polycarbonate/ABS plastic case, polycarbonate door, polycarbonate hinges and latches, 316 SST (stainless steel) hardware Remote indicator: polycarbonate/ABS plastic	Nelson Sentinel Series Basic Chlorine Sentinel is equivalent to Hach CM130 Chlorine Monitor.
Sample Flow Rate	250 mL/min minimum	N/A	250 mL/min minimum	Nelson Sentinel Series Basic Chlorine Sentinel is identical to Hach CM130 Chlorine Monitor.

Item	Subject Device Nelson Sentinel Series Basic Chlorine Sentinel	Predicate Device UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips	Reference Device Hach CM130 Chlorine Monitor	Comparison
Sample Pressure	270 kPa – 530 kPa (40 psi – 80 psi)	N/A	2.76 bar – 6.89 bar (40 psi – 100 psi) nominal; pressure spikes 8.27 bar (120 psi) or less	<p>Nelson Sentinel Series Basic Chlorine Sentinel is equivalent to Hach CM130 Chlorine Monitor.</p> <p>The upper limit of the sample pressure of Nelson Sentinel Series Basic Chlorine Sentinel is lower than that of Hach CM130 Chlorine Monitor. This difference in sample pressure does not affect the intended use or safety and effectiveness of the device.</p>

Item	Subject Device Nelson Sentinel Series Basic Chlorine Sentinel	Predicate Device UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips	Reference Device Hach CM130 Chlorine Monitor	Comparison
Sample Temperature	15 – 40°C (60 – 105°F)	N/A	15 – 30°C (60 – 85°F)	<p>Nelson Sentinel Series Basic Chlorine Sentinel is equivalent to Hach CM130 Chlorine Monitor.</p> <p>The upper limit of the sample temperature of Nelson Sentinel Series Basic Chlorine Sentinel is higher than that of Hach CM130 Chlorine Monitor. This difference in sample temperature does not affect the intended use or safety and effectiveness of the device.</p>

Item	Subject Device Nelson Sentinel Series Basic Chlorine Sentinel	Predicate Device UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips	Reference Device Hach CM130 Chlorine Monitor	Comparison
Operating Temperature	15 – 40°C (60 – 105°F)	N/A	15 – 30°C (60 – 85°F)	<p>Nelson Sentinel Series Basic Chlorine Sentinel is equivalent to Hach CM130 Chlorine Monitor.</p> <p>The upper limit of the operating temperature of Nelson Sentinel Series Basic Chlorine Sentinel is higher than that of Hach CM130 Chlorine Monitor. This operating temperature difference does not affect the intended use or safety and effectiveness of the device.</p>

Item	Subject Device Nelson Sentinel Series Basic Chlorine Sentinel	Predicate Device UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips	Reference Device Hach CM130 Chlorine Monitor	Comparison
Operating Humidity	35 - 85% RH	N/A	5 – 90% non-condensing at 30°C (85°F) maximum	Nelson Sentinel Series Basic Chlorine Sentinel is equivalent to Hach CM130 Chlorine Monitor. Hach CM130 Chlorine Monitor has a wider humidity range than Nelson Sentinel Series Basic Chlorine Sentinel. This difference in operating humidity has no impact on the intended use or the safety and effectiveness of the device.

Testing

The following testing has been performed for Nelson Sentinel Series Basic Chlorine Sentinel:

Electrical Safety / Electromagnetic Compatibility

Testing was performed in accordance with the following standards:

- IEC 61010-1 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 1: General Requirements
- IEC 61326-1 Electrical Equipment for Measurement, Control, and Laboratory Use – EMC Requirements – Part 1: General Requirements

Shelf-Life

Shelf life testing has been performed for the ammonium sulfate reagent used in the device.

Performance – Bench

Bench Testing has been performed to verify the performance of the Nelson Sentinel Series Basic Chlorine Sentinel, which includes:

- Linearity Study
- Precision Study
- Limit of Blank, Limit of Quantitation, Limit of Detection Study
- Method Comparison Study
- Peristaltic Pump and Tubing Validation
- Free Chlorine Study
- 15 Weeks Calibration Study

Software

Software validation has been performed for the software component of the Nelson Sentinel Series Basic Chlorine Sentinel.

Substantial Equivalence Conclusions

In conclusion, the Nelson Sentinel Series Basic Chlorine Sentinel has the same intended use as the predicate device as they both can be used to monitor the level of total chlorine (free chlorine/chloramines) and do not come into direct contact with feed water used to prepare dialysate. The proposed device is intended as an auxiliary monitoring system while the UltraLow Total Chlorine and E-Z Chek Sensitive Total Chlorine Test strips are intended as primary chlorine detection technology. The technological characteristics were compared to the Hach CM130 Chlorine Monitor reference device and performance testing demonstrates that the proposed device is safe and effective despite differences in technology. The proposed Nelson Sentinel Series Basic Chlorine Sentinel is substantially equivalent to Ultra Low Total Chlorine and E-Z Chek Sensitive Total Chlorine Test Strips.

Conclusion

The 510(k) Pre-market Notification for Nelson Sentinel Series Basic Chlorine Sentinel contains adequate information and data to determine that Nelson Sentinel Series Basic Chlorine Sentinel is safe and effective as the legally marketed predicate device.