April 11, 2025

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

Re: K243898
Trade/Device Name: Chlorine Sentinel II
Regulation Number: 21 CFR 876.5665
Regulation Name: Water Purification System For Hemodialysis
Regulatory Class: Class II
Product Code: MSY, PSX
Dated: March 18, 2025
Received: March 18, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Maura Rooney -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
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Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243898

Device Name

Chlorine Sentinel II

Indications for Use *(Describe)*

The Chlorine Sentinel II is intended for use by hemodialysis professionals as a secondary chlorine device to provide continuous monitoring of Combined Chlorine. It is not intended to replace the primary method of monitoring chlorine as part of the hemodialysis water treatment system. It functions completely independent of the water treatment system 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.

NELSON ENVIRONMENTAL TECHNOLOGIES, INC.

NELSON WATER SYSTEMS
FOR HEMODIALYSIS

FDA-Cleared Systems for Hemodialysis 510k) # 993877
FDA-Cleared Systems for Nelson Sentinel Series Basic Chlorine Sentinel 510k) # 193169
ISO 13485:2016 Certified Certificate# C2023-05290

6. Summary of 510(k)

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

Submitter: Nelson Environmental Technologies, Inc.
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Date Prepared: 2024 December 18

Device Name and Classification

Trade Name: Chlorine Sentinel II
Common Name: Water Purification System for Hemodialysis
Classification: Class II
Regulation Number: 21 CFR 876.5665 Water Purification System for Hemodialysis
Classification Panel: Gastroenterology/Urology
Product Code: MSY, PSX

Predicate Device:

	Predicate Device
Trade Name	Nelson Basic Chlorine Sentinel Basic Chlorine Sentinel
Common Name	Basic Chlorine Sentinel
510(k) Submitter / Holder	Nelson Environmental Technologies, Inc.
510(k) Number	K193169/S001
Regulation Number	21 CFR 876.5665 Water purification system for hemodialysis
Classification Panel	Gastroenterology/Urology
Product Code	PSX, FIP

Device Description

Chlorine Sentinel II is a complete system that attaches to the drain of a hemodialysis water treatment system sample port. It detects dissolved combined chlorine in concentrations at or above 10 PPB by primary detection technology. It self-monitors for maintenance-required conditions and loss of electrical power.

The Chlorine Sentinel II is self-testing. It uses chlorinated city water to automatically test the chlorine detecting functionality of the device once a day and records if the test passed, failed to detect chlorine, or didn't rinse out after detecting chlorine.

The device is designed to use as little water as possible. The sampling water is only used for the length of time that it takes for the chlorine test to be completed. The customer determines how frequently the test needs to be taken from every 5 minutes to every 20 minutes. The user also sets the start time and end time for each day of the week.

The Chlorine Sentinel II has two combined chlorine concentration set points. The user can set a warning set-point at a value of 0.01 PPM to 0.09 PPM. Once the chlorine concentration exceeds this value, the device will alarm at 2-HZ to warn the user of chlorine present at that set-point. The second set-point is factory set at 0.10 PPM.

A chlorine concentration equal to or above the 0.10 PPM set-point will activate the buzzers and the red chlorine alarm indicators at 5 HZ 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 alarms can be by-passed. When by-passed the pulsing lights will turn solid and the buzzer will double click over 15 minutes.

The front cover of the device has two screens. The screen of the chlorine monitor indicates the presence of combined chlorine when the value is not 0.000. The touch screen is used to enter user data and show the statuses of the device.

Indications for Use

The Chlorine Sentinel II is intended for use by hemodialysis professionals as a secondary chlorine device to provide continuous monitoring of Combined Chlorine. It is not intended to replace the primary method of monitoring chlorine as part of the hemodialysis water treatment system. It functions completely independent of the water treatment system does not come into direct contact with feed water used to prepare dialysate.

Risk Analysis Method

Chlorine Sentinel II 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 Chlorine Sentinel II is essentially the same as the Nelson Basic Chlorine Sentinel with the following differences:

1. A Touch Screen and PLC replace the electrical components of the Basic Chlorine Sentinel;
2. It is inside one enclosure instead of two;
3. User can set a warning set-point for chlorine concentration;
4. User can set the start and stop times for each day;
5. User can set the sampling rate times from 5 minutes to 20 minutes;
6. The Touch Screen highlights alarm statuses;
7. Includes water Shut-off Device.

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	Predicate Device	Reference Device	Comparison to Predicate Device (Noted reference device comparison for items that are closer to it)
	Chlorine Sentinel II	**Nelson Sentinel Series Basic Chlorine Sentinel**	**Hach CM130 Chlorine Monitor**	
Intended Use/ Indications for Use	The Chlorine Sentinel II is an instrument that is intended for use by hemodialysis professionals as a secondary chlorine monitor to indicate the presence of combined chlorine in feed water used in hemodialysis systems It can be used as a secondary chlorine test. It is not intended to be used as a primary chlorine detection device	Nelson Sentinel Series Basic Chlorine Sentinel is indicated for detection of Total Chlorine in Water. Nelson Sentinel Series Basic Chlorine Sentinel is indicated for testing water used to prepare dialysate.	Hach CM130 is intended for use in hemodialysis Water treatment systems to read Total Chlorine concentration.	Same as Predicate
Provides Exact Chlorine Value?	No; Intended to indicate chlorine presence above 0.01 PPM and reference value.	Approximate values	Yes; presents an exact chlorine value on its display intended to be used to make clinical decisions	Same as Predicate
Provides Exact Combined Chlorine Value?	Yes; presents an exact combined chlorine value on its display	Yes	No; measures total chlorine which may be free, combined dissolved, and suspended chlorinated solids	Same as Predicate
Detection Chemistry/ Technology	Direct measuring polarographic sensor utilizing a special polymeric membrane.	Direct measuring polarographic sensor utilizing a special polymeric membrane.	DPD Colorimetric Method	Same as Predicate
Chlorine Sensor Type	Polarography (Amperometry)	Polarographic sensor	Photometric sensor	Same as Predicate
Interference with other compounds in potable water	None	None	Chlorinated organics/suspended solids	Same as Predicate
Reagents	None (Ammonium Sulfate if used with municipal free chlorine disinfected water)	Ammonium sulfate	Indicator solution (DPD indicator with potassium iodide), buffer solution	Same as Predicate

Reagent Delivery	N/A	Peristaltic pump	Peristaltic pump	Same
Type of Chlorine Detected	Dissolved Combined Chlorine, free chlorine to a lesser degree	Dissolved Combined Chlorine, free chlorine to a lesser degree	Total Chlorine (free chlorine plus total chloramines)	Same as Predicate
Detection Range	> 0.01 mg/L	0.05 mg/L Cl_2 – 0.15 mg/L Cl_2	0.03 mg/L Cl_2 – 0.20 mg/L Cl_2	Same as Predicate
Chlorine Level Alarm	0.1 mg/L Cl_2	0.1 mg/L Cl_2	0.1 mg/L Cl_2	Same as Predicate
Warning Chlorine Set-point	0.01PPM – 0.09PPM	NA	NA	Different. Warning set-point is a customer requested feature to allow them to be proactive when the presence of combined chlorine is detected versus reactive when the AAMI standard chlorine concentration is reached.
Self-Testing	Automatic testing daily with test passed notification, manual reset. Manual testing for maintenance and calibration	Automatic testing daily with test passed notification, manual reset. Manual testing for maintenance and calibration	None	Same as Predicate
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.	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.	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.	Same as Predicate
Water Sample Conditioning and Delivery	Automatic	Automated	Automated	Same as Predicate
Measurement Interval	5 -30 Minutes	Continuous	5 minutes	Different. Chlorine Sentinel II only uses water during the sampling cycle. This significantly reduces the amount of water used over the life of the device

Alarms/ Alerts	Controller: Multi-color Touch Screen highlighted Colors (green for power indication, Red for Chlorine over set-points, yellow for maintenance notification, orange for past chlorine detected, blue for auto-test passed) and a buzzer Remote Module: Four colors (green for power indication, red for chlorine alerts, yellow for maintenance notification, blue for auto test passed) and a buzzer	Controller: Three colors (green for power indication, 2 yellow, and red for alerts) and a buzzer Remote Module: Three color lights (green for power indication, 2 yellow, and a red for alerts) and a buzzer	Analyzer: Two colors (amber and red) on the display and three sounds for notifications. 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.	Different. Auto-test successful light is blue instead of yellow (chlorine Detected) in the predicate device Lights and buzzers pulse at two different rates depending on user-set set-point and 0.10 mg/L set-point for combined chlorine concentration.
Sounds	Piezoelectric buzzer providing 5 Hz pulses for chlorine over 0.10 mg/L, 2 Hz chlorine over user-defined Warning Set-Point or for maintenance notification, solid if PLC failure. 15-minute double chirp if any alarms have been by-passed		Analyzer: Two different sounds identify a hardware alarm or high chlorine alarm. Remote Indicator: Three different sounds identify a power-loss alarm, hardware alarm or high chlorine alarm.	Different. Predicate device has solid buzzer. Chlorine Sentinel II has added two pulse frequencies to indicate Chlorine over set-points and action-required notifications.
Measurement Log	Unlimited		3000 measurements maximum	Different. Predicate device has no log.
Measurement Point	Between the primary and secondary carbon tanks (filters)	After the secondary carbon filter, before the reverse osmosis (RO) machine.	Between the primary and secondary carbon tanks (filters).	Same as Predicate
Device Location	Remote Module is located in the nurse's station; all other components are located in the water room	Remote Module is located in the nurse's station; all other components are located in the water room	Remote indicator is located in the patient room; all other components are located in the water room	Same as Predicate

Enclosure	V0 Fire-rated ABS, IP66 rated with door closed. Remote Indicator Material: PC/ABS	V0 Fire-rated ABS, IP66 rated with door closed. Remote Indicator Material: PC	Enclosure Rating: IP52 rated with the door closed. Enclosure Material: PC/ABS case, PC door, PC hinges & latches, 316 SST hardware. Remote Indicator Material: PC/ABS	Same as Predicate
External Drain Sample Port	On right side wall of enclosure designed for easy access of sample bottles.	On right side wall of enclosure designed for easy access of sample bottles.		Same as Predicate
Enclosure to protect electronics from splashing or spills	Physical splash barrier	NA	Yes	Predicate had separate enclosures to separate electronics from water. Substantially equivalent. Similar to CM130
Water Treatment Required	No	No	No	Same as Predicate
Device Components	Analyzer, Remote Indicator	Controller, Probe/Tester, Remote Module	Analyzer, Remote Indicator	Substantially equivalent to Predicate
Control Mechanism	PLC – Siemens 1200 Touch Screen - Mitsubishi	Microcontroller	Microcontroller	Different. Substantially equivalent to Reference
Maintenance	Quarterly	Quarterly	Monthly	Same as Predicate
Data Logger	SD Card	No data logger	3000 measurements maximum	Different. Substantially equivalent to Reference
Status Outputs	1. Combined chlorine over set-point (Default 0.100) 2. Analyzer Self-Diagnostic system failures or maintenance required. 3. Auto-Test Passed notification 4. Loss of analyzer signal 5. Loss of analyzer electrical power 6. Auto-Test Failed	5 water treatment status outputs - RO shut-down, flood, loss of electricity, device maintenance, and high chlorine	Two levels of chlorine, power statuses	Substantially equivalent to Predicate

Data Outputs	MODBUS TCP		MODBUS TCP	
Data History	The measurement history is available through the Ethernet connection. Measurement History & Event History can be copied to an SD card as two separate files.	NA	The measurement history is available through the Ethernet connection. Measurement History & Event History can be copied to an SD card as two separate files.	Different. Substantially equivalent to Reference
Display	17.9 cm (7") Color Touch Screen Monitor: 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	Monitor: 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	10.9 cm (4.3 in.) color display, backlit LCD< WQVGA	Different. Predicate has no Touch Screen. Substantially equivalent to Reference
System Power	24 VDC	24VDC	24 VDC	Same as Predicate
Power Requirement	110 – 240 VAC line power	110 – 240 VAC line power	100 – 240 VAC, 50/60 Hz, 1 A max	Same as Predicate
Mounting	Water Room: Wall Remote Indicator: Wall	Water Room: Wall Remote Indicator: Wall	Analyzer: Wall Remote Indicator: 1.1 kg (2.5 lbs.)	Same as Predicate
Dimensions	Controller: 38.0 x 56.0 x 18.5 cm Remote Module: 14 x 11 x 5 cm	Controller: 32.0 x 42.0 x 16.5 cm (12.5 x 16.5 x 6.5 in.) Probe/Tester: 18.0 x 28.0 x 18.5 cm (7.1 x 11.0 x 7.3 in.) Remote Module: 20.0 x 14.5 x 10.0 cm (7.9 x 5.7 x 3.9 in.)	Analyzer: 37.0 x 53.8 x 22.6 cm (14.6 x 21.2 x 8.9 in.) Remote indicator: 12.3 x 19.4 x 10.7 cm (4.8 x 11.6 x 4.2 in.)	Different. Predicate has 2 enclosures. Chlorine Sentinel II has the components of both predicate devices in 1 enclosure.

Weight	Controller: 6.5 kg (14.3 lbs.) Remote Module: 0.25 kg (0.5 lb.)	Controller: 6.5 kg (14.3 lbs.) Probe/Tester: 3 kg (6.6 lbs.) Remote Module: 1 kg (2.2 lbs.)	Analyzer: 8.9 kg (19.6 lbs.) Remote Indicator: 1.1 kg (2.5 lbs.)	Substantially equivalent to Predicate except only 1 enclosure
Materials	ABS Plastic enclosure, PVC, Stainless steel, aluminum, polyethylene, electronic components, 3-D printed material: PLA	Controller: PVC and stainless-steel monitor, ABS plastic enclosure Probe/Tester: ABS plastic enclosure Remote Module: ABS plastic enclosure	Analyzer: polycarbonate/ABS plastic case, polycarbonate door, polycarbonate hinges and latches, 316 SST (stainless steel) hardware Remote indicator: polycarbonate/ABS plastic	Same as Predicate
Sample Flow Rate	250/350 mL/min minimum	250 mL/min minimum	250 mL/min minimum	Same as Predicate
Sampling Schedule	Site set between 00:00 and 23:59 for M-W-F, T-T-S, and Sunday	NA	Continuous if not manually put into “Idle Mode” and manually taken out of “Idle Mode”	Different. Not available on Predicate
Sampling Duration	1-2 Minute	Continuous 24/7	5 Minutes	Different. Not available on Predicate
Sample Pressure	270 kPa – 530 kPa (40 psi – 80 psi)	270 kPa – 530 kPa (40 psi – 80 psi)	2.76 bar – 6.89 bar (40 psi – 100 psi) nominal; pressure spikes 8.27 bar (120 psi) or less	Same as Predicate
Sample Temperature	15 – 40° (60 – 105°F)	15 – 40°C (60 – 105°F)	15 – 30°C (60 – 85°F)	Same as Predicate
Sampling Sediment Filter	City water cartridge sediment Filter: 5” x 2.5” x 1-µm		Requires less than 15 µm	Same as Predicate
Includes water Shut-off Device	Yes	No	No	Different. Customer requested assessory
Operating Temperature	15 – 40°C (60 – 105°F	15 – 40°C (60 – 105°F)	15 – 30°C (60 – 85°F)	Same as Predicate
Operating Humidity	35 – 85% RH	35 - 85% RH	5 – 90% non-condensing at 30°C (85°F) maximum	Same as Predicate

Testing

The following testing has been performed for Chlorine Sentinel II:

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 60601-1-2:2020 (Ed. 4.1) Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

Shelf-Life

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

Performance – Bench

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

- Linearity Study to CLSI standard EP06-A

- Limit of Blank, Limit of Quantitation, Limit of Detection Study to CLSI standard EP17-A2

Software

Software validation has been performed for the software component of the Chlorine Sentinel II.

Substantial Equivalence Conclusions

In conclusion, the Chlorine Sentinel II indications for use are the same as the predicate device Nelson Sentinel Series Basic Chlorine Sentinel, related to the detection of Chlorine in Water and testing water used to prepare dialysate.

The performance characteristics and testing demonstrate that the Chlorine Sentinel II are substantially equivalent to the predicate device the Nelson Sentinel Series Basic Chlorine Sentinel.

The technological characteristics for the detection of chlorine are the same as the predicate device, the Nelson Sentinel Series Basic Chlorine Sentinel. It is different in that the mechanical push buttons and switches are replaced with a PLC and color touch screen. In this aspect it is closer the Hach CM130 Chlorine Monitor.

As both the predicate device and the reference device are FDA certified, the Chlorine Sentinel II is as safe and effective as they are.

Conclusion

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