March 17, 2026

Serim Research
Amy Sheets
Quality Operations and Regulatory Affairs Manager
3506 Reedy Dr.
Elkhart, Indiana 46514

Re: K253863
Trade/Device Name: GUARDIAN™ Quick Dip Residual Chlorine (5212)
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System And Accessories
Regulatory Class: Class II
Product Code: FJK
Dated: February 17, 2026
Received: February 17, 2026

Dear Amy Sheets:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253863

Device Name
GUARDIAN™ Quick Dip Residual Chlorine (5212)

Indications for Use *(Describe)*

GUARDIAN™ Quick Dip Residual Chlorine (5212) Test Strips provide a convenient means for indicating the concentration of chlorine bleach (sodium hypochlorite) remaining in the solution used to rinse dialysate lines following disinfection of hemodialysis equipment.

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

Prepared:	December, 2025
Submitter:	Serim Research Corporation
Address	3506 Reedy Drive Elkhart IN 46514
Phone: **Fax:**	574-264-3440 574-266-6222
Contact:	Amy Sheets Quality Operations and Regulatory Affairs Manager
Device Trade Name:	GUARDIAN™ Quick Dip Residual Chlorine (5212)
Common or Usual Name:	Free Chlorine Reagent Strips
Device Classification Name:	Filter, Blood, Dialysis
Product Code:	FKJ
Class:	II
Regulation Number:	876.5820
Substantial Equivalence:	The GUARDIAN™ Quick Dip Residual Chlorine (5212) is substantially equivalent to Serim® GUARDIAN™ RESIDUAL CHLORINE/ K901734
Subject Device Description:	The device is a semiquantitative, single use, reagent test strip made up of a 0.20-inch square reagent pad that has been chemically treated to detect residual free chlorine in water. The pad is affixed to one end of a 3.25 inch by 0.20-inch white opaque polystyrene strip.
Subject Device Intended Use:	GUARDIAN™ Quick Dip Residual Chlorine (5212) Test Strips provide a convenient means for indicating the concentration of chlorine bleach (sodium hypochlorite) remaining in the solution used to rinse dialysate lines following disinfection of hemodialysis equipment.

Indications for use: GUARDIAN™ Quick Dip Residual Chlorine (5212) Test Strips provide a convenient means for indicating the concentration of chlorine bleach (sodium hypochlorite) remaining in the solution used to rinse dialysate lines following disinfection of hemodialysis equipment.

Technological Characteristics: The GUARDIAN™ Quick Dip Residual Chlorine (5212) Test Strips contain one indicator, a non-ionic surfactant, reducing agent, and other inactive ingredients. Free chlorine reacts with the indicator to form shades of yellow-green complex. The amount of green color formed is dependent on the concentration of free chlorine in the sample. The color blocks on the label are related to chlorine concentration in terms of parts per million (ppm). The device is used to detect free chlorine concentrations between 0 and 5 ppm. Refer to table 1 for more information.

Predicate Device: Serim® GUARDIAN™ RESIDUAL CHLORINE/ K901734

Predicate Device Description: The device is a semi-quantitative, single use, reagent test strip made up of a 0.20-inch square reagent pad that has been chemically treated to detect residual free chlorine in water. The pad is affixed to one end of a 3.25 inch by 0.20-inch white opaque polystyrene strip.

Predicate Device Intended use: Test Strips provide a convenient means for indicating the concentration of chlorine bleach (sodium hypochlorite) remaining in the solution used to rinse dialysate lines following disinfection of hemodialysis equipment

Performance: The performance of the GUARDIAN™ Quick Dip Residual Chlorine (5212) Test Strips was evaluated using water samples, sodium hypochlorite was added to give a range of free chlorine levels. The performance of the GUARDIAN™ Quick Dip Residual Chlorine (5212) Test Strips is equivalent to the predicate device, Serim® GUARDIAN™ RESIDUAL CHLORINE Reagent Strips.

Table 1 Summarize the technological characteristic for the subjected device against predicate device

Table 1 Summary of Technological Characteristics Table

Parameters	Subject Device	Predicate Device	*Comparison*
Identification	GUARDIAN™ Quick Dip Residual Chlorine (5212)	Serim® GUARDIAN™ RESIDUAL CHLORINE	*Different*
Intended use	Test Strips provide a convenient means for indicating the concentration of chlorine bleach (sodium hypochlorite) remaining in the solution used to rinse dialysate lines following disinfection of hemodialysis equipment.	Test Strips provide a convenient means for indicating the concentration of chlorine bleach (sodium hypochlorite) remaining in the solution used to rinse dialysate lines following disinfection of hemodialysis equipment	*Similar*
Indications for use	Test Strips provide a convenient means for indicating the concentration of chlorine bleach (sodium hypochlorite) remaining in the solution used to rinse dialysate lines following disinfection of hemodialysis equipment.	Test Strips provide a convenient means for indicating the concentration of chlorine bleach (sodium hypochlorite) remaining in the solution used to rinse dialysate lines following disinfection of hemodialysis equipment	*Similar*
Analyte	Free Chlorine	Free Chlorine	*Similar*
Indicator strip	Paper indicator adhered to a plastic handle	Paper indicator adhered to a plastic handle	*Similar*
Technological characteristics	Free chlorine oxidizes the redox indicator, to form a color that is directly proportional to the amount of chlorine in the sample	Free chlorine oxidizes the redox indicator to form a color that is directly proportional to the amount of chlorine in the sample	*Similar*
Indicator agents	Redox indicator	Redox indicator	*Similar*
Semi-quantitative Test Method	Dip the test strip for 2 seconds	Immerse indicator pad of test strip in sample solution	*Different*
	Gently shake strip to remove excess sample	Move strips back and forth vigorously for 30 seconds	
	Compare the pad to color chart within 5 seconds	Remove strip and compare to color chart within 10 seconds	
Color Blocks	0, 0.5, 1.0, 2.0, and 5.0 ppm	0, 0.5, 1.0, 2.0, and 5.0 ppm	*Similar*

Color Development	Yellow / shades of green	White / shades of purple	*Different*

Summary of Non-Clinical Performance Date:

The performance of the GUARDIAN™ Quick Dip Residual Chlorine (5212) Test Strips was evaluated in non-clinical tests in a range of free chlorine concentration at 0, 0.5 and 1.0 ppm free chlorine. The results show that the proposed device is an effective monitor of residual concentration of free chlorine.

Table 2 summarizes the non-clinical testing performed by Serim Research to demonstrate safety and effectiveness of the GUARDIAN™ Quick Dip Residual Chlorine (5212) Test Strips in monitoring the concentration of free chlorine in rinse water.

Table 2

Study	Results
Performance	Met reference value 0, 0.5, and 1.0 ppm free chlorine.
Instructions for Use Validation	Met reference value with +/- 1 second dip time validation, and + 8 seconds read time validation.
Close Bottle Shelf-Life Stability	Met reference value for 12 months (Accelerated)
Open Bottle Use-Life Stability	Met reference value for 30 months (Accelerated)
Comparative Sensitivity and Specificity	Met reference value at <0.5ppm and ≥ 0.5ppm free chlorine concentration.
Light study	Met reference value under cool white-fluorescent light and day light.

The performance of the GUARDIAN™ Quick Dip Residual Chlorine (5212) Test Strips was evaluated using water samples, sodium hypochlorite was added to give a range of free chlorine levels. The performance of the GUARDIAN™ Quick Dip Residual Chlorine (5212) Test Strips is equivalent to the predicate device, Serim® GUARDIAN™ RESIDUAL CHLORINE Reagent Strips.

Conclusion: The GUARDIAN™ Quick Dip Residual Chlorine (5212) Test Strips have the same intended use as the predicate device. Both test strips measure the free chlorine levels in water. The GUARDIAN™ Quick Dip Residual Chlorine (5212) Test Strips have no characteristics that raise new types of safety or effectiveness questions. The GUARDIAN™ Quick Dip Residual Chlorine (5212) test strips can be used to detect residual chlorine levels in rinse water from dialysis equipment which had been disinfected with chlorine bleach