June 3, 2025

Serim Research Corporation
Jackie Nelson
Director of Quality Operations
3506 Reedy Drive
Elkhart, Indiana 46514

Re: K251035
Trade/Device Name: DISINTEK™ PA Test Strips
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: April 3, 2025
Received: April 3, 2025

Dear Jackie Nelson:

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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.06.03 16:06:06 -04'00'

for: Christopher K. Dugard, M.S.
Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251035

Device Name

DISINTEK™ PA Test Strips

Indications for Use *(Describe)*

The Serim™ DISINTEK™ PA Test Strip is a chemical indicator for use in determining whether the concentration of peracetic acid, the active ingredient in the high-level disinfectant RAPICIDE™ PA HLD solution, is above the 850 ppm PAA minimum recommended concentration (MRC) established for RAPICIDE™ PA HLD at both 30°C and 20°C.

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

510(k):	K251035
Prepared:	April 01, 2025
Revised:	June 2, 2025
Submitter:	Serim Research Corporation
Address:	3506 Reedy Drive Elkhart IN 46514
Phone: **Fax:**	574-264-3440 574-266-6222
Contact:	Jackie Nelson Director of Regulatory Operations
Device Trade Name:	DISINTEK™ PA Test Strip
Common or Usual Name:	Indicator for RAPICIDE™ PA HLD High-Level Disinfectant
Device Classification Name:	Chemical Indicators for Liquid Chemical Germicide. (b) Class II (Physical/Chemical Sterilization Process Indicator).
Product Code:	JOJ
Class:	II
Regulation Number:	21CFR 880.2800
Predicate Device:	MEDIVATORS™ RAPICIDE™ PA Minimum Required Concentration (MRC) Test Strips, REF ML02-0118; K152394.
Device Description:	The device is a qualitative, single use, reagent chemical indicator made up of a 0.2-inch x 0.2-inch indicator pad that has been chemically treated to detect peracetic acid above or below the Minimum Recommended Concentration established for RAPICIDE™ PA High-Level Disinfectant. The

indicator pad is affixed to one end of a 3.25-inch by 0.2-inch white plastic handle.

Intended Use: The Serim™ DISINTEK™ PA Test Strip is a chemical indicator for use in determining whether the concentration of peracetic acid, the active ingredient in the high-level disinfectant RAPICIDE™ PA HLD solution, is above the 850 ppm PAA minimum recommended concentration (MRC) established for RAPICIDE™ PA HLD at both 30°C and 20°C.

Indications for Use: The Serim™ DISINTEK™ PA Test Strip is a chemical indicator for use in determining whether the concentration of peracetic acid, the active ingredient in the high-level disinfectant RAPICIDE™ PA HLD solution, is above the 850 ppm PAA minimum recommended concentration (MRC) established for RAPICIDE™ PA HLD at both 30°C and 20°C.

Technological Characteristics: The DISINTEK PA Test Strip contains colorimetric indicators, a catalyst, a reducing agent, and other non-reactive components. The reaction process involved with the test pad is based on a multi-step reaction. The first step involves a reaction in which the reducing agent reacts with PAA in the RAPICIDE PA HLD up to the Minimum Recommended Concentration (MRC) and neutralizes it. The next step is a reaction of the remaining peracetic acid with a catalyst, which then reacts with colorimetric indicators at peracetic acid levels above 850 ppm, resulting in a green pad coloration. The device will reliably indicate if the peracetic acid concentration is above or below the MRC level of 850 ppm peracetic acid at both 30°C and 20°C. Refer to Table 1 for more information.

Table 1: Summary of Technological Characteristics Table

Parameters	DISINTEK™ PA Test Strips	MEDIVATORS™ RAPICIDE™ PA Minimum Required Concentration (MRC) Test Strips, REF ML02-0118; K152394	Comparison
Analyte	PAA in RAPICIDE™ PA HLD Solution.	PAA in RAPICIDE™ PA HLD Solution.	Same
Indicator strip	0.2" x 0.2" test paper attached to a plastic handle	0.2" x 0.2" test paper attached to a plastic handle	Same
Chemistry	A reducing agent reacts with PAA up to the Minimum Recommended Concentration (MRC) and neutralizes it. If the PAA concentration in the solution is > MRC, the remaining PAA ***reacts with a halide and redox indicators***, creating a colored compound. The test pad changes from ***yellow to green***.	The chemical principle of the test is based on the ***oxidation of iodide to iodine*** by peracetic acid. A ***dark complex*** is obtained in the presence of starch.	Different
Indicator Agents	***Redox indicators***	***Iodide*** ***Starch***	Different
Chemicals Present in the Device	Polymers, ***halide***, reducing agent, ***redox indicators***, ***background dye***.	***Starch, iodide***	Different
Minimum Time of Color Change	25-30 seconds	30 seconds	Same

Parameters	DISINTEK™ PA Test Strips	MEDIVATORS™ RAPICIDE™ PA Minimum Required Concentration (MRC) Test Strips, REF ML02-0118; K152394	Comparison
Details of Chemical Formulation	A reducing agent reacts with PAA up to the Minimum Recommended Concentration (MRC) and neutralizes it. If the PAA concentration in the solution is > MRC, the remaining PAA ***reacts with a halide and redox indicators***, creating a colored compound. The test pad changes from ***yellow to green***.	The chemical principle of the test is based on the ***oxidation of iodide to iodine*** by peracetic acid. A ***dark complex*** is obtained in the presence of starch.	Different
Results	A test pad which is similar in color to the FAIL color blocks indicates the solution is ≤ 850 ppm PAA (MRC). If the color of the test pad is similar to the PASS blocks, the solution is ≥ 1100 ppm PAA.	Any test strip color other than solid black is a FAIL result (i.e., ≤ 850 ppm PAA MRC). A solid black color indicates a PASS result (i.e., > 850 ppm PAA).	Same
"PASS" Indication	***Green***	***Solid Black***	Different
Bold Italic text indicates differences between the proposed and predicate device.			

The DISINTEK PA Test Strips have the same intended use as the predicate device. Both devices measure the potency of peracetic acid in the disinfectant solution to determine whether it is above or below the Minimum Recommended Concentration at both 30°C and 20°C. The differences between the proposed peracetic acid test strip and the predicate device are the colorimetric indicators. The differences do not impact the safety and effectiveness of the subject device. The risk to safety and effectiveness of the color differences between the two devices is mitigated by using validated directions for use and a validated color chart that accurately conveys how a user is to use the device and interpret the color at the appropriate read time.

Summary of Non-Clinical Performance Data: The performances of the DISINTEK PA Test Strips were evaluated in non-clinical tests in a range of concentrations below, at, and above the MRC at both 30°C and 20°C. The results show that the proposed device is an effective monitor of the concentration of peracetic acid in the RAPICIDE PA HLD solution when used as directed by the manufacturer.

Table 2 summarizes the non-clinical testing performed by Serim Research to demonstrate safety and effectiveness of the DISINTEK PA Test Strips in monitoring the concentration of RAPICIDE PA HLD high-level disinfectant solutions. A further discussion of each individual study follows the table.

Table 2: DISINTEK™ PA Test Strips: Performance Testing Summary

Study	Results
Dynamic Range	**Met Acceptance Criteria:** Negative response at concentrations at or below MRC, positive responses at higher concentrations.
Instructions for Use Validation	**Met Acceptance Criteria:** Negative response at concentrations at or below MRC, positive responses at higher concentrations.
Closed Bottle Shelf-Life Stability	**Met Acceptance Criteria:** Met specifications for 18 months (unopened).
Open Bottle Use-Life Stability	**Met Acceptance Criteria:** Met specification for 18 months (opened).
Comparative Sensitivity and Specificity	**Met Acceptance Criteria:** Comparative sensitivity and specificity of 1

Dynamic Range: The dynamic range of the DISINTEK PA Test Strips was evaluated below, at, and above the MRC using RAPICIDE PA HLD high-level disinfectant solutions. The test strip yielded acceptable performance with 100% FAIL results at and below the 850 ppm PAA (MRC) and PASS results above the MRC at both 30°C

and 20°C.

Instructions for Use Validation: The instructions for use of the DISINTEK PA Test Strips were evaluated below, at, and above the MRC using RAPICIDE PA HLD high-level disinfectant solutions at both 30°C and 20°C. The chemical indicators yielded acceptable performance with a 1-2 second dip time and a sideblot time at 25 seconds + 5 seconds for 30°C solutions and 30 seconds + 5 seconds for 20°C solutions. The test strips yielded acceptable performance with 100% FAIL results at and below the MRC and PASS results above the MRC.

Closed Bottle Shelf-Life Stability: The closed bottle shelf-life of the DISINTEK PA Test Strips was evaluated below, at, and above the MRC with RAPICIDE PA HLD high-level disinfectant solutions with test strip storage ≥ 10°C and up to 32°C. The test strip yielded acceptable performance out to a minimum of 18 months shelf-life from ≥ 10°C storage up to 32°C, with data collection ongoing. The test strip yielded acceptable performance with 100% FAIL results at and below the MRC and PASS results above the MRC. An 18-month shelf-life is claimed for the DISINTEK PA Test Strips.

Open Bottle Use-Life Stability: The open bottle use-life of the DISINTEK PA Test Strips was evaluated below, at, and above the MRC with RAPICIDE PA HLD high-level disinfectant solutions at both 30°C and 20°C at constant high humidity storage (~ 80% RH) and repeated openings of the test strip bottle. The test strips yielded acceptable performance out to a minimum of 18 months open bottle use-life, with data collection ongoing. The chemical indicator yielded acceptable performance with 100% FAIL results at and below the MRC and PASS results above the MRC. An 18- month open bottle use-life is claimed for the DISINTEK PA Test Strips.

Comparative Sensitivity and Specificity: The DISINTEK PA Test Strips were compared to the predicate device, MEDIVATORS™ RAPICIDE™ PA Minimum Required Concentration (MRC) Test Strips, REF ML02-0118 using comparison studies. A comparative sensitivity of 100% and comparative

specificity of 100% was found for the DISINTEK PA test strips at both 30°C and 20°C.

Analytic Specificity – Bioburden: The sensitivity of the DISINTEK PA Test Strips to bioburden was evaluated below, at, and above the MRC using RAPICIDE PA HLD high-level disinfectant solutions at both 30°C and 20°C using fetal bovine serum and hard water. The chemical indicator yielded acceptable performance with 100% FAIL results at and below the MRC and 100% PASS results above the MRC.

Analytic Specificity – Other Disinfectants: The sensitivity of the DISINTEK PA Test Strips to other peracetic acid disinfectants was evaluated at use concentrations similar to the RAPICIDE PA HLD disinfectant at normal dilution concentrations (1:1:48). The test strip yielded PASS results using these disinfectants. These results are documented in the Product Insert for the test strip.

Conclusion: Based on the non-clinical tests performed, the subject device, DISINTEK PA Test Strip, is as safe, as effective, and performs as well as or better than the legally marketed predicate device, MEDIVATORS™ RAPICIDE™ PA Minimum Required Concentration (MRC) Test Strips, REF ML02-0118, K152394, Class II (21CFR 880.2800), Product code JOJ.

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