December 2, 2020

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

Re: K202565
Trade/Device Name: WAVICIDE-OPA MEC Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: September 4, 2020
Received: September 4, 2020

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 (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,

Ryan Ortega -S

For CAPT Elizabeth Claverie, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202565

Device Name

WAVICIDE-OPA® MEC Indicator

Indications for Use *(Describe)*

The WAVICIDE-OPA® MEC Indicator is a chemical indicator for use in determining whether the concentration of ortho-phthalaldehyde, the active ingredient in the high-level disinfectant WAVICIDE-OPA® Solution, is above or below the minimum effective concentration (MEC) established for WAVICIDE-OPA Solution.

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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510(K) SUMMARY

510(k):	K202565
Prepared:	September 4, 2020
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:	WAVICIDE-OPA MEC Indicator
Common or Usual Name:	Indicator for WAVICIDE-OPA (OPA) 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:	Serim® DISINTEK™ OPA Test Strips, Serim Research Corporation, P/N 5121; K081370.
Device Description:	The device is a qualitative, single use, reagent chemical indicator made up of a 0.4-inch x 0.4-inch indicator pad that has been chemically treated to detect OPA above or below the Minimum Effective Concentration. The indicator pad is affixed to one end of a 3.25 inch by 0.4-inch white opaque plastic handle.

Intended Use: The WAVICIDE-OPA MEC Indicator is a qualitative chemical indicator for use in determining whether the concentration of OPA, the active ingredient in Medical Chemical Corporation's WAVICIDE-OPA Solution, is above or below the established Minimum Effective Concentration (MEC) established by the solution manufacturer.

Indications for Use: The WAVICIDE-OPA® MEC Indicator is a chemical indicator for use in determining whether the concentration of *ortho*-phthalaldehyde, the active ingredient in the high-level disinfectant WAVICIDE-OPA® Solution, is above or below the minimum effective concentration (MEC) established for WAVICIDE-OPA Solution.

Technological Characteristics: The WAVICIDE-OPA MEC Indicator contains a reacting chemical, a reducing agent, and other non-reactive components. The reaction process involved with the test pad is based on a three-step reaction. The first step involves generating a reducing agent in the pad. The second step involves a reaction in which the reducing agent reacts with OPA at a concentration equivalent to 0.3% (MEC) to neutralize it. A second reaction then occurs in which OPA reacts at levels above 0.3% with an indicator, resulting in a green pad coloration. The device will reliably indicate if the OPA concentration is above or below the MEC level of 0.3% OPA. Refer to Table 1 for more information.

Table 1: Summary of Technological Characteristics Table

Parameters	WAVICIDE-OPA MEC Indicators	Serim® DISINTEK OPA Test Strip (K081370)	Comparison
Analyte	OPA in ***WAVICIDE-OPA Solution***	OPA in ***Cidex OPA Solution***	Similar
Indicator Strip	0.4" x 0.4" test paper attached to a plastic handle	0.4" x 0.4" test paper attached to a plastic handle	Same

Parameters	WAVICIDE-OPA MEC Indicators	Serim® DISINTEK OPA Test Strip (K081370)	Comparison
Chemistry	Sodium sulfite reacts to form bisulfite in the test pad. Bisulfite reacts with OPA up to the Minimum Effective Concentration (MEC) and neutralizes it. If the OPA concentration in the solution is > MEC, the remaining OPA reacts with glycine contained in the test strip pad, creates a colored compound and causes a color change of the test pad from blue to green.	Sodium sulfite reacts to form bisulfite in the test pad. Bisulfite reacts with OPA up to the Minimum Effective Concentration (MEC) and neutralizes it. If the OPA concentration in the solution is > MEC, the remaining OPA reacts with glycine contained in the test strip pad, creates a colored compound and causes a color change of the test pad from blue to green.	Same
Indicator Agents	Glycine	Glycine	Same
Chemicals Present in the Device	Acidic Polymer, pH Buffer, Sodium Sulfite, Complexing Agents, Surfactant, Glycine, Blue Background Dye.	Acidic Polymer, pH Buffer, Sodium Sulfite, Complexing Agents, Surfactant, Glycine, Blue Background Dye.	Same
Minimum Time of Color Change	60 seconds	60 seconds	Same
Details of Chemical Formulation	Sodium sulfite reacts to form bisulfite in the test pad. Bisulfite reacts with OPA up to the Minimum Effective Concentration (MEC) and neutralizes it. Excess OPA then reacts with glycine forming a colored compound. A blue dye in the pad enhances the color distinction. The pH buffer provides the appropriate pH conditions for the reaction.	Sodium sulfite reacts to form bisulfite in the test pad. Bisulfite reacts with OPA up to the Minimum Effective Concentration (MEC) and neutralizes it. Excess OPA then reacts with glycine forming a colored compound. A blue dye in the pad enhances the color distinction. The pH buffer provides the appropriate pH conditions for the reaction.	Same

Parameters	WAVICIDE-OPA MEC Indicators	Serim® DISINTEK OPA Test Strip (K081370)	Comparison
Results	A test pad which is similar in color to the FAIL color blocks indicates the solution is ≤ 0.3% OPA. If the color of the test pad is similar to the PASS blocks, the solution is > 0.3% OPA.	A test pad which is similar in color to the FAIL color blocks indicates the solution is ≤ 0.3% OPA. If the color of the test pad is similar to the PASS blocks, the solution is > 0.3% OPA.	Same
"PASS" Indication	Green colored pad.	Green colored pad.	Same
Bold Italic text indicates differences between the proposed and predicate device.			

The WAVICIDE-OPA MEC Indicators have the same intended use as the predicate device. Both devices measure the potency of *ortho*-phthalaldehyde (OPA) in disinfectant solution, to determine whether it is above or below the Minimum Effective Concentration. The difference between the proposed OPA indicator and the predicate device is the use in different commercial preparations of OPA disinfectant.

Summary of Non-Clinical Performance Data: The performances of the WAVICIDE-OPA MEC Indicators were evaluated in non-clinical tests in a range of concentrations below, at, and above the MEC. The results show that the proposed device is an effective monitor of the concentration of WAVICIDE-OPA 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 WAVICIDE-OPA MEC Indicators in monitoring the concentration of WAVICIDE-OPA high-level disinfectant solutions. A further discussion of each individual study follows the table.

Table 2: WAVICIDE-OPA MEC Indicators: Performance Testing Summary

Study	Results
Dynamic Range	**Met Acceptance Criteria:** Negative response at concentrations at or below MEC, positive responses at higher concentrations.
Instructions for Use Validation	**Met Acceptance Criteria:** Negative response at concentrations at or below MEC, positive responses at higher concentrations.
Closed Bottle Shelf-Life Stability	**Met Acceptance Criteria:** Met specifications after storage of labeled shelf life of 18 months (unopened).
Open Bottle Use-Life Stability	**Met Acceptance Criteria:** Met specification for 6 months (opened).
Comparative Sensitivity and Specificity	**Met Acceptance Criteria:** Comparative sensitivity and specificity of 1

Dynamic Range: The dynamic range of the WAVICIDE-OPA MEC Indicators was evaluated below, at, and above the MEC using WAVICIDE-OPA high-level disinfectant solutions. The chemical indicator yielded acceptable performance with 100% FAIL results at and below the MEC and PASS results above the MEC.

Instructions for Use Validation: The instructions for use of the WAVICIDE-OPA MEC Indicators were evaluated at and above the MEC using WAVICIDE-OPA high-level disinfectant solutions. The chemical indicators yielded acceptable performance with a 20 ± 5 second dip time, a ≤ 1 second to 5 second sideblot time, and a 60 ± 5 second read time. The chemical indicator yielded acceptable performance with 100% FAIL results at and below the MEC and PASS results above the MEC.

Closed Bottle Shelf-Life Stability: The closed bottle shelf-life of the WAVICIDE-OPA MEC Indicators was evaluated at and above the MEC with WAVICIDE-OPA high-level disinfectant solutions at ambient room temperature up to 32°C

storage. The chemical indicator yielded acceptable performance out to a minimum of 18 months shelf-life from ambient room temperature up to 32°C, with data collection ongoing. The chemical indicator yielded acceptable performance with 100% FAIL results at and below the MEC and PASS results above the MEC. An 18-month shelf-life is claimed for the WAVICIDE-OPA MEC Indicators.

Open Bottle Use-Life Stability: The open bottle use-life of the WAVICIDE-OPA MEC Indicators was evaluated at and above the MEC with WAVICIDE-OPA high-level disinfectant solutions at constant high humidity storage (≥ 80% RH) and repeated openings of the chemical indicator bottle. The chemical indicator yielded acceptable performance out to a minimum of 6 months open bottle use-life, with data collection ongoing. The chemical indicator yielded acceptable performance with 100% FAIL results at and below the MEC and PASS results above the MEC. A 6-month open bottle use-life is claimed for the WAVICIDE-OPA MEC Indicators.

Comparative Sensitivity and Specificity: The WAVICIDE-OPA MEC Indicators were compared to the predicate device, Serim DISINTEK OPA test strips using comparison studies. A comparative sensitivity of 100% and comparative specificity of 100% was found for both devices. There was 100% overall agreement with values for prepared samples in both cases.

Analytic Specificity – Bioburden: The sensitivity of the WAVICIDE-OPA MEC Indicators to bioburden was evaluated at and above the MEC using WAVICIDE-OPA high-level disinfectant solutions and fetal bovine serum and hard water. The chemical indicator yielded acceptable performance with 100% FAIL results at and below the MEC and PASS results above the MEC.

Analytic Specificity – Other Disinfectants: The sensitivity of the WAVICIDE-OPA MEC Indicators to other aldehyde-based disinfectants was evaluated at their respective full-strength concentrations. The indicator yielded some PASS results using these disinfectants, depending on the disinfectant. These results are documented in the

Product Insert for the Indicators.

Conclusion: Based on the non-clinical tests performed, the subject device, WAVICIDE-OPA MEC Indicator, is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Serim® DISINTEK™ OPA Test Strips # 5121, K081370, Class II (21CFR 880.2800), Product code JOJ.