April 2, 2020

Serim Research Corporation
Jackie Nelson
Director Of Quality Operations
3506 Reedy Drive
Elkhard, Indiana 46514

Re: K192445
Trade/Device Name: Qwikcheck™ Chemical Indicators
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: February 26, 2020
Received: February 27, 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,

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)*
K192445

Device Name

QwikCheck™ Chemical Indicators

Indications for Use *(Describe)*

The QwikCheck™ Chemical Indicator is a chemical indicator for use in determining whether the concentration of peracetic acid, the active ingredient in CS Medical's TD-12 Solution, is above or below the manufacturer's established Minimum Recommended Concentration (MRC) of 1750 ppm.

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):	K192445
Prepared:	March 30, 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:	QwikCheck™ Chemical Indicators
Common or Usual Name:	Indicator for peracetic acid (PAA) 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:	21 CFR 880.2800
Predicate Device:	Serim® GUARDIAN™ Peracetic Acid Test Strips, Serim Research Corporation, P/N 5106; K910320.
Device Description:	The device is a qualitative, single use, reagent chemical indicator made up of a 0.20-inch square indicator pad that has been chemically treated to detect peracetic acid above or below the Minimum Recommended Concentration. The indicator pad is affixed to one end of a 3.25 inch by 0.20-inch white opaque plastic handle.

Intended Use: The QwikCheck™ Chemical Indicator is a qualitative chemical indicator dedicated for use in determining whether the concentration of peracetic acid, the active ingredient in CS Medical's TD-12 Solution, is above or below the established Minimum Recommended Concentration (MRC) according to the solution manufacturer.

Indications for Use: The QwikCheck™ Chemical Indicator is a chemical indicator for use in determining whether the concentration of peracetic acid, the active ingredient in CS Medical's TD-12 Solution, is above or below the manufacturer's established Minimum Recommended Concentration (MRC) of 1750 ppm.

Technological Characteristics: The QwikCheck™ Chemical Indicators contains two reacting chemicals, a reducing agent, and other non-reactive compounds. The reaction process involved with the test pad is based on a two-step reaction. The first step involves a reaction in which the reducing agent reacts with peracetic acid at a concentration equivalent to 1750 ppm (MRC) to neutralize it. A second reaction then occurs in which PAA at levels above 1750 ppm reacts with one chemical and then complexes with a second chemical, resulting in a brown pad coloration. The device will reliably indicate if the PAA concentration is above or below the MRC level of 1750 ppm PAA. Refer to Table 1 for more information.

Table 1: Summary of Technological Characteristics Table

Parameters	**QwikCheck™ Chemical Indicator (K192445)**	**Serim® GUARDIAN™ Peracetic Acid Test Strip (K910320)**	**Comparison**
Analyte	Peracetic acid in **TD-12 Solution**	Peracetic acid in **dialyzer reuse solutions**	Similar
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

Parameters	QwikCheck™ Chemical Indicator (K192445)	Serim® GUARDIAN™ Peracetic Acid Test Strip (K910320)	Comparison
Chemistry	Sodium thiosulfate reacts with PAA up to the minimum recommended concentration (MRC) and neutralizes it. If the PAA concentration in the solution is > MRC, iodide reacts with excess PAA, creating iodine which then complexes with starch to create a colored complex and causes a color change of the test pad.	Sodium thiosulfate reacts with PAA up to the minimum recommended concentration (MRC) and neutralizes it. If the PAA concentration in the solution is > MRC, iodide reacts with excess PAA, creating iodine which then complexes with starch to create a colored complex and causes a color change of the test pad.	Same
Indicator Agent(s)	Starch and iodide.	Starch and iodide.	Same
Chemicals Present in Device	Starch, potassium iodide, sodium thiosulfate, and pH buffer.	Starch, iodide, sodium thiosulfate, and pH buffer.	Similar
Minimum Time of Color Change	30 seconds.	10 seconds.	Different
Details of Chemical Formulation	Sodium thiosulfate reacts with PAA up to the minimum recommended concentration (MRC) and neutralizes it. Excess PAA then oxidizes the iodide forming iodine, which then complexes with starch to produce a brown coloration. The pH buffer provides the appropriate pH conditions for the reaction.	Sodium thiosulfate reacts with PAA up to the minimum recommended concentration (MRC) and neutralizes it. Excess PAA then oxidizes the iodide forming iodine, which then complexes with starch to produce a black/blue coloration. The pH buffer provides the appropriate pH conditions for the reaction.	Similar

Parameters	QwikCheck™ Chemical Indicator (K192445)	Serim® GUARDIAN™ Peracetic Acid Test Strip (K910320)	Comparison
Results	A test pad which is similar in color to the FAIL color block indicates the solution is ≤ **1750 ppm**. If the color of the test pad is similar to the PASS block, the solution is > **1750 ppm**.	If the indicator pad is predominantly or entirely white, record the result as "FAIL"; the peracetic acid concentration is at or below **400 ppm**. If the indicator pad is predominantly or entirely gray/blue, black or brown, record the result as "PASS"; the peracetic acid concentration is at or above **800 ppm**.	Different
"PASS" Indication	Dark brown.	**Gray / blue**, black or brown.	Similar
Bold text indicates differences between the proposed and predicate device.			

The QwikCheck™ Chemical Indicators have the same intended use as the predicate device. Both devices measure the potency of peracetic acid (PAA) in disinfectant solution, to determine whether it is above or below the Minimum Recommended Concentration. The difference between the proposed PAA indicator and the predicate device is the use in different concentrations of commercial preparations of PAA.

Summary of Non-Clinical Performance Data:

The performances of the QwikCheck™ Chemical Indicators were evaluated in non-clinical tests in a range of concentrations below, at, and above the MRC. The results show that the proposed device is an effective monitor of the concentration of TD-12 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 QwikCheck Chemical Indicators in monitoring the concentration of TD-12 peracetic acid high-level disinfectant solutions. A further discussion of each individual study follows the table.

Table 2: 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 after storage of labeled shelf life of 12 months (unopened).
Open Bottle Use-Life Stability	**Met Acceptance Criteria:** Met specification for 3 months (opened).
Comparative Sensitivity and Specificity	**Met Acceptance Criteria:** Comparative sensitivity and specificity of 1

Dynamic Range: The dynamic range of the QwikCheck Chemical Indicators was evaluated below, at, and above the MRC using TD-12 peracetic acid high-level disinfectant solutions. The chemical indicator yielded acceptable performance with 100% FAIL results at and below the MRC and PASS results above the MRC.

Instructions for Use Validation: The instructions for use of the QwikCheck Chemical Indicators were evaluated at and above the MRC using TD-12 peracetic acid high-level disinfectant solutions. The chemical indicator yielded acceptable performance with an immediate dip/removal from solution time, a 5 ± 1 second sideblot time, a time to blot of ≤ 1 second, and a 30 ± 5 second read time. The chemical indicator 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 QwikCheck Chemical Indicators was evaluated at and above the MRC with TD-12 peracetic acid high-level disinfectant solutions at ambient room temperature up to 32°C storage. The chemical indicator yielded acceptable performance out to a minimum 15 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 MRC and PASS results above the MRC. A conservative 12-month shelf-life is claimed.

Open Bottle Use-Life Stability: The open bottle use-life of the QwikCheck Chemical Indicators was evaluated at and above the MRC with TD-12 peracetic acid 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 5 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. A conservative 3-month open bottle use-life is claimed.

Comparative Sensitivity and Specificity: The QwikCheck Chemical Indicators were compared to the predicate device, Serim GUARDIAN Peracetic Acid 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 QwikCheck Chemical Indicators to bioburden was evaluated at and above the MRC using TD-12 peracetic acid high-level disinfectant solutions and fetal bovine serum. The chemical indicator yielded acceptable performance with 100% FAIL results at and below the MRC and PASS results above the MRC.

Analytic Specificity – Other Disinfectants: The sensitivity of the QwikCheck Chemical Indicators to other disinfectants was evaluated at and above the MRC using TD-12 peracetic acid high-level disinfectant solutions and the following disinfectants: hydrogen peroxide and sodium hypochlorite. The chemical indicator yielded 100% FAIL results for all conditions tested.

Conclusion: Based on the non-clinical tests performed, the subject device, QwikCheck™ Chemical Indicator is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Serim® GUARDIAN™ Peracetic Acid Test Strips, K910320, Class II (21CFR 880.2800), Product code JOJ.