DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 14, 2015

STERIS Corporation
Anthony Piotrkowski
Senior Manager, Regulatory Affairs
5960 Heisley Road
Mentor, Ohio 44060-1834

Re: K143333
Trade/Device Name: Revital-Ox™ RESERT™ R60 Solution Test Strip
Regulation Number: 21 CFR 880.2800
Regulation Name: Chemical Indicator/Physical/Chemical sterilization process indicator
Regulatory Class: II
Product Code: JOJ
Dated: March 16, 2015
Received: March 17, 2015

Dear Mr. Piotrkowski:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

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Clinical Deputy Director
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Erin I. Keith, M.S.
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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143333

Device Name

Revital-Ox™ RESERT™ R60 Solution Test Strip

Indications for Use *(Describe)*

The Revital-Ox™ RESERT™ R60 Solution Test Strip is a high level disinfectant concentration monitor dedicated for use with Revital-Ox™ RESERT™ High Level Disinfectant. The purpose of the Revital-Ox™ RESERT™ R60 Solution Test Strip is to determine whether the concentration of hydrogen peroxide, the active ingredient in Revital-Ox™ RESERT™ High Level Disinfectant, is above the minimum recommended concentration (MRC) of 1.5%.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary
For
Revital-Ox™ RESERT™ R60 Solution Test Strip
K143333

Sponsor:
STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 357-9198

Manufacturer:
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Hamilton Industrial Park
Leicester
United Kingdom LE5 1QZ

Contact: Anthony Piotrkowski
Regulatory Affairs Manager
Telephone: (440) 392-7473
Fax No: (440) 357-9198
E-mail: tpiotrko@steris.com

Summary Date: April 8, 2015

1. Device Name

Trade Name:	Revital-Ox™ RESERT™ R60 Solution Test Strip
Common/usual Name:	Chemical Indicator
Device Class	Class II
Classification Name:	Physical/chemical sterilization process indicator (21 CFR 880.2800 (b), Product Code JOJ)

2. Predicate Device

K102296 Verify® Chemical Monitoring Strip for Resert™ Solution

- This predicate has not been subject to a design-related recall.

3. Description of Device

The Revital-Ox™ RESERT™ R60 Solution Test Strip is a chemical indicator strip consisting of an absorbent paper pad impregnated with reactive chemicals that is adhesively bonded to one end of a polymer film. The polymer strip has a window to facilitate viewing of the color change. The Revital-Ox™ RESERT™ R60 Solution Test Strip has been developed to monitor Revital-Ox™ RESERT™ High Level Disinfectant solution (originally cleared as Resert XL HLD High Level Disinfectant) that has a minimum recommended concentration (MRC) of 1.5%. The Revital-Ox™ RESERT™ R60 Solution Test Strip is dipped into a working solution of Revital-Ox™ RESERT™ High Level Disinfectant and the resultant color reaction is viewed through the window to determine if the solution is above the MRC and thus still suitable for use.

4. Intended Use

The Revital-Ox™ RESERT™ R60 Solution Test Strip is a high level disinfectant concentration monitor dedicated for use with Revital-Ox™ RESERT™ High Level Disinfectant. The purpose of the Revital-Ox™ RESERT™ R60 Solution Test Strip is to determine whether the concentration of hydrogen peroxide, the active ingredient in Revital-Ox™ RESERT™ High Level Disinfectant, is above the minimum recommended concentration (MRC) of 1.5%.

Table 5-1. Indications for Use Comparison

Proposed Revital-Ox™ RESERT™ R60 Solution Test Strip	**Predicate K102296 Verify® Chemical Monitoring Strip for Resert Solutions Version 2**	**Comparison**
The Revital-Ox™ RESERT™ R60 Solution Test Strip **is a high level disinfectant concentration monitor dedicated for use with** Revital-Ox™ RESERT™ **High Level Disinfectant**. **The purpose of the** Revital-Ox™ RESERT™ R60 Solution Test Strip **is to determine whether the concentration of hydrogen peroxide, the active ingredient in** Revital-Ox™ RESERT™ **High Level Disinfectant, is above the minimum recommended concentration (MRC) of 1.5%.**	The Verify® Chemical Monitoring Strip for Resert Solutions Version 2 **is a high level disinfectant concentration monitor dedicated for use with** Resert® XL HLD **High-Level Disinfectant. The purpose of the** Verify® Chemical Monitoring **Strip** for Resert Solutions Version 2 **is to determine whether the concentration of** a Resert® XL HLD **High-Level Disinfectant solution is above the minimum recommended concentration (MRC) of 1.5%.**	Change in intended use is limited to a name change to reflect the brand/name change of Resert® XL HLD High-Level Disinfectant to Revital-Ox™ RESERT™ High Level Disinfectant and to specify that the strips monitors the active ingredient in the disinfectant solution.

Bolded text is identical between predicate and proposed devices

5. Description of Safety and Substantial Equivalence

The proposed and predicate devices are single use chemical indicator strips that monitor the hydrogen peroxide concentration in Revital-Ox™ RESERT™ High Level Disinfectant solution.

The purpose of this submission is to clear design changes to the Revital-Ox™ RESERT™ R60 Solution Test Strip for ease of read and longer shelf life.

Table 5-2 summarizes the comparison between the proposed device, Revital-Ox™ RESERT™ Solution Test Strip, and the predicate.

Table 5-2. Technological Comparison to Predicate

	Proposed	Predicate	Comparison
Substrate	Absorbent Paper	Absorbent Paper	Same
Indicator / reaction	Colorimetric sulfite pH-based reaction	Colorimetric starch/iodide reaction	The strip does not contact patients. Impact of the difference in reactive chemistry on safety was evaluated through literature review. Efficacy of the proposed strip is summarized in Table 5.3 below
Backing	Polypropylene	Polypropylene	Same

	Proposed	Predicate	Comparison
Color change	Yellow to blue/purple	Blue to black	Blinded testing demonstrated proper interpretation of strips.
Detection	greater than 1.5% hydrogen peroxide	greater than 1.5% hydrogen peroxide	Same
Use temperature range	20 °C minimum	20 -24 °C	Efficacy of the proposed strip at or above 20 °C was demonstrated through testing under simulated use, testing with contaminants, testing after exposure to aggressive chemicals and blind interpretation of exposed strips.
Viewing	Viewing window, paper on back of strip	Paper on front of strip	Blinded testing demonstrated proper interpretation of strips.
Shelf-life, unopened	1 year	6 months	Testing was performed to support increased unopened bottle shelf life.
Shelf-life, opened	11 days to date	180 days	

Table 5-3 summarizes the verification activities that were performed, with their respective acceptance criteria and results, to demonstrate that the Revital-Ox™ RESERT™ R60 Solution Test Strip is substantially equivalent to the claimed predicate device when used according to its instructions for use. The product effectively determines whether or not the concentration of the use solution of Revital-Ox™ RESERT™ High Level Disinfectant is greater than 1.5% hydrogen peroxide. These studies confirm that the device's performance meets the requirements of its pre-defined acceptance criteria and intended uses.

Table 5-3 Performance Test Summary

Test	Acceptance Criteria	Comparision
Performance	Equivalent performance to the predicate in pass and fail conditions for simulated use.	**Equivalent**
Specificity	Incomplete color change when exposed to tap water only or to Revital-Ox™ RESERT™ High Level Disinfectant solution with peroxide below MRC or no peroxide	**The proposed strip does not change when exposed to the active ingredient (hydrogen peroxide) alone as the predicate does. The proposed strip requires the active ingredient of the disinfectant to be in its final form thus demonstrating greater specificity to the disinfectant solution than the predicate. The proposed strip performs equivalently to the predicate in water alone or in disinfectant without the active ingredient.**
Contaminants	Equivalent performance to the predicate in pass and fail conditions in the presence of organic and inorganic contaminants in the test solution	**Equivalent**
Exposure to aggressive chemicals	Equivalent performance to the predicate in pass and fail conditions	**The proposed strip demonstrated failing results under pass conditions after exposure to aggressive chemicals. The product labeling includes a warning to store away from aggressive chemicals. This same warning is in the labeling of the predicate device.**
Blind study testing	Equivalent performance to the predicate in pass and fail conditions	**Equivalent**
Shelf life	Meet performance specifications at each time point after storage in different environments	**Performance testing of the proposed device out to one year was performed.**
In-use (open bottle)	Meet performance specifications at each time point after storage in different environments	**Performance testing of the proposed device up to 11 days was performed.**

6. Conclusion

The Revital-Ox™ RESERT™ R60 Solution Test Strip intended for use with Revital-Ox™ RESERT™ High Level Disinfectant is substantially equivalent to the predicate device, Verify® Chemical Monitoring Strip for Resert™ Solution. Based on the nonclinical tests performed the subject device is as safe, as effective and performs at least as safely and effectively as the legally marketed predicate devices, Class II (21 CFR 880.2800, Product code JOJ).