DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 12, 2016

Steris Corporation
Bill Brodbeck, Ph.D.
Director, Regulatory Affairs
5960 Heisley Road
Mentor, Ohio 44060

Re: K152630
Trade/Device Name: VERIFY® STEAM Integrating Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization process indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: April 11, 2016
Received: April 12, 2016

Dear Dr. Brodbeck:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
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)*
K152630

Device Name
VERIFY® STEAM Integrating Indicator

Indications for Use *(Describe)*
The integrating indicator is designed to chemically react over time with the critical parameters of steam sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles:

Steam Sterilization Cycles:
- 250°F/121°C, 30 minutes Gravity
- 270°F/132°C, 4 minutes Dynamic Air Removal
- 270°F/132°C, 15 minutes Gravity
- 275°F/135°C, 3 minutes Dynamic Air Removal
- 275°F/135°C, 10 minutes Gravity

Steam Sterilization Cycles (IUSS):
- 270°F/132°C, 4 minutes Dynamic Air Removal
- 270°F/132°C, 3 minutes Gravity
- 270°F/132°C, 10 minutes Gravity
- 275°F/135°C, 3 minutes Dynamic Air Removal
- 275°F/135°C, 3 minutes Gravity
- 275°F/135°C, 10 minutes Gravity

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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STERIS®

510(k) Summary
for
VERIFY® STEAM Integrating Indicator

Sponsor Facility
STERIS Corporation
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Mentor, OH 44060
Phone: (216) 354-2600
Fax No: (216) 639-4459

Manufacturing Facility
Dana Products, Inc.
11457 Melrose Street
Franklin Park, IL 60131

Contact: Bill Brodbeck, Ph.D.
Director, Regulatory Affairs
Telephone: (440) 392-7690
Fax No: (440) 357-9198
e-mail: William_brodbeck@steris.com

Submission Date: May 12, 2016

1. Device Name

Trade Name:	VERIFY® STEAM Integrating Indicator
Device Classification:	Class II
Common/usual Name:	Indicator, physical/chemical sterilization process
Classification Name:	Indicator, physical/chemical sterilization process (21 CFR 880.2800, JOJ)

2. Predicate Device

Dana Steam Sterilization Integrator (K012195), Dana Products Inc.

3. Description of Device

The VERIFY® STEAM Integrating Indicator is a single use device used by healthcare providers to monitor steam sterilization cycles. The VERIFY® STEAM Integrating Indicator is included in a pack or load in a steam sterilizer and the load is processed in accordance with the sterilizer manufacturer's directions. Prior to the use of the processed items, the Integrator is observed. If the dark bar on the device enters the ACCEPT (OK) window, the integrator is read as a PASS to indicate that the steam sterilization criteria for the cycle have been met. If the dark bar on the device does not enter the ACCEPT (OK), the integrator is read as a FAIL, indicating that sufficient steam sterilization criteria has not been met and processed materials should be subjected to another steam sterilization cycle prior to use.

4. Intended Use

The integrating indicator is designed to chemically react over time with the critical parameters of steam sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles:

Steam Sterilization Cycles:
- 250°F/121°C, 30 minutes Gravity
- 270°F/132°C, 4 minutes Dynamic Air Removal
- 270°F/132°C, 15 minutes Gravity
- 275°F/135°C, 3 minutes dynamic air removal
- 275°F/135°C, 10 minutes Gravity

Steam Sterilization Cycles (IUSS):
- 270°F/132°C, 4 minutes Dynamic Air Removal
- 270°F/132°C, 3 minutes Gravity
- 270°F/132°C, 10 minutes Gravity
- 275°F/135°C, 3 minutes dynamic air removal
- 275°F/135°C, 3 minutes Gravity
- 275°F/135°C, 10 minutes Gravity

5. Description of Safety and Substantial Equivalence

The proposed and predicate devices are single use integrating indicators for use in monitoring steam sterilization cycles. The products are identical in design with the exception of the labeling, which is being revised as a result of rebranding the device under the VERIFY product family (STERIS purchased Dana Products Inc. in March, 2015). The differences between the proposed VERIFY® STEAM Integrating Indicator and the predicate Dana Steam Sterilization Integrator are limited to expanding the indications for use statement to include use of the device to monitor various steam sterilization cycles. These differences do not raise any new issues of safety and efficacy. Performance testing has been conducted for monitoring all claimed steam sterilization cycles in accordance with the Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators.

6. Technological Characteristics

The proposed and predicate devices are single use integrating indicators for use in monitoring particular steam sterilization cycles. The device components, mechanism of action, and endpoint are the same as the predicate's and when exposed to the defined processing conditions, the proposed and predicate devices exhibit a visible migration of the included chemistry to indicate that stated values have been achieved.

Table 5-1 contains a comparison of technological characteristics and specifications of the proposed VERIFY® STEAM Integrating Indicator to the predicate Dana Steam Sterilization Integrator.

Table 5-1. Device Comparison Table

Feature	Proposed VERIFY® STEAM Integrating Indicator	K012195 Dana Steam Sterilization Integrator	Comparison
Intended use	The integrating indicator is designed to chemically react over time with the critical parameters of steam sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles: Steam Sterilization Cycles: •250°F/121°C, 30 minutes Gravity •270°F/132°C, 4 minutes Dynamic Air Removal •270°F/132°C, 15 minutes Gravity •275°F/135°C, 3 minutes dynamic air removal •275°F/135°C, 10 minutes Gravity Steam Sterilization Cycles (IUSS): •270°F/132°C, 4 minutes Dynamic Air Removal •270°F/132°C, 3 minutes Gravity •270°F/132°C, 10 minutes Gravity •275°F/135°C, 3 minutes dynamic air removal •275°F/135°C, 3 minutes Gravity •275°F/135°C, 10 minutes Gravity	Dana Steam Sterilization Integrators are intended to be used to monitor critical parameters in steam sterilization cycles in healthcare facilities. The critical parameters for which the integrators will respond are time and temperature (when steam is present). The end point is determined by the migration of the steam sensitive dye to an area marked safe on the indicator. The integrators are intended to be used in 30 minute gravity cycles at 250 degrees F and 3 minute gravity and pre-vacuum cycles at 270 degrees F.	The intended use statement has been updated to reflect specific uses of the subject device as well expand the indicated cycles to include those commonly utilized in healthcare facilities. Testing in conformance with the Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators for integrating indicators addresses any concerns regarding the safety and efficacy of the proposed device in regards to the claimed steam sterilization cycles.

Feature	Proposed VERIFY® STEAM Integrating Indicator	K012195 Dana Steam Sterilization Integrator	Comparison
Device design - components	Backing material with embossed cavity containing temperature sensitive chemical and coloring dye, wicking strip, covered with laminated paper containing labeling and windows.	Backing material with embossed cavity containing temperature sensitive chemical and coloring dye, wicking strip, covered with laminated paper containing labeling and windows.	Device design and components are identical with exception of the printed labeling.
Indicator agent	Proprietary formulation	Proprietary formulation	The indicator agent is identical to the predicate.
Sterilization method and cycles	Per intended use above.	30 minute gravity cycles at 250 degrees F and 3 minute gravity and pre-vacuum cycles at 270 degrees F.	The intended cycles vary between indicators. Intended cycles for the proposed device will be verified and validated in accordance with the Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators.
Mechanism of action	Proprietary	Proprietary	Mechanism of action is identical to predicate.
Endpoint specifications	The end point is determined by the migration of the steam sensitive dye to an area marked ACCEPT (OK) on the indicator. Endpoint is reached at the stated value (SV) for each claimed temperature. Endpoint is not reached at the stated value - 15% time and/or -1°C.	The end point is determined by the migration of the steam sensitive dye to an area marked safe on the indicator. Endpoint is reached at the stated value (SV) for each claimed temperature. Endpoint is not reached at the stated value - 15% time and/or -1°C.	The end point is the same for proposed and predicate devices.

Feature	Proposed VERIFY® STEAM Integrating Indicator	K012195 Dana Steam Sterilization Integrator	Comparison
Comparison of integrator stated values at biological indicator growth-negative cycle conditions	Integrator does not reach endpoint before the biological indicator is inactivated.	Integrator does not reach endpoint before the biological indicator is inactivated	Same performance observed.
Shelf-life	5 years	5 years	Proposed and predicate devices have the identical design and therefore carry the same shelf-life claims.
Standard / Guidance	Conforms to the Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators for integrating indicators and ANSI/AAMI/ISO 11140-1:2014: Sterilization of Health Care Products - Chemical Indicators - Part 1: General Requirements.	Conforms to ST60: Sterilization of Health Care Products - Chemical Indicators - Part 1: General Requirements.	Both proposed and predicate devices meet the applicable standards at the time of their introduction into interstate commerce.

7. Performance Testing

Performance testing was conducted to verify that the proposed VERIFY® STEAM Integrating Indicator meets the requirements for integrating indicators in accordance with the Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators for integrating indicators as well as ANSI/AAMI/ISO 11140-1:2014.

Table 5-2 summarizes the verification activities that were performed, with their respective acceptance criteria and results, to demonstrate that the proposed VERIFY® STEAM Integrating Indicator is as safe and is as effective. These studies confirm that the proposed device's performance meets the requirements of its pre-defined acceptance criteria and intended uses, and qualify the proposed device for use in the claimed steam sterilization cycles.

Stated Values

The subject device (integrator indicator) testing was performed in a bier vessel using the following stated values shown below at the following temperatures (see Table 5-2). The integrator indicator showed a passing result when the chemicals in the subject device reacted to all critical parameters in the bier vessel.

Table 5-2. Verification Results Summary

Test of 3 Lots	Acceptance Criteria	Study Result
BIER Vessel Testing	Pass result at SV for each temperature claimed Stated values are: • 23.0 min at 121°C • 2.0 min at 132 °C • 1.2 min at 135 °C	**PASS**
	Fail result at 15% below SV for each temperature claimed	**PASS**
	Fail result at 1°C below SV for each temperature claimed	**PASS**
Simulated Use Testing in Claimed Sterilization Cycles	100% Pass result under pass conditions	**PASS**
	100% Fail result under fail conditions	**PASS**
Dry Heat Testing	Fail result when exposed to 140°C dry heat for 30 min	**PASS**
Verification of integrator stated values at biological indicator growth-negative cycle conditions	Integrator does not reach endpoint before the biological indicator is inactivated	**PASS**
Offset/ Bleeding	Integrator shall not bleed or offset	**PASS**

The results of the VERIFY® STEAM Integrating Indicator performance testing demonstrate that both perform as intended in the claimed steam sterilization cycles and the proposed device is substantially equivalent to the predicate device.

8. Conclusion

The proposed device design is identical to that of predicate device, with the exception of the relabeling under the VERIFY brand. The intended use of the proposed device adds additional cycles and clarification of use conditions. The VERIFY® STEAM Integrating Indicator is as safe and is as effective when used to monitor the claimed steam sterilization cycles and is substantially equivalent to the predicate device.