January 21, 2022

STERIS Corporation
Jennifer Nalepka
Lead Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44060

Re: K213412
Trade/Device Name: VERIFY STEAM Integrating Indicator, VERIFY STEAM Integrating Indicator 5CM
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: October 18, 2021
Received: October 19, 2021

Dear Jennifer Nalepka:

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 Clarence W. Murray, III, PhD
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213412

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 a 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, 5 minutes Dynamic Air Removal
- 270°F/132°C, 6 minutes Dynamic Air Removal
- 270°F/132°C, 7 minutes Dynamic Air Removal
- 270°F/132°C, 8 minutes Dynamic Air Removal
- 270°F/132°C, 9 minutes Dynamic Air Removal
- 270°F/132°C, 10 minutes Dynamic Air Removal
- 270°F/132°C, 15 minutes Gravity
- 273°F/134°C, 4 minutes Dynamic Air Removal
- 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213412

Device Name
VERIFY STEAM Integrating Indicator 5CM

Indications for Use *(Describe)*
The integrating indicator is designed to chemically react over time with the critical parameters of a 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, 5 minutes Dynamic Air Removal
- 270°F/132°C, 6 minutes Dynamic Air Removal
- 270°F/132°C, 7 minutes Dynamic Air Removal
- 270°F/132°C, 8 minutes Dynamic Air Removal
- 270°F/132°C, 9 minutes Dynamic Air Removal
- 270°F/132°C, 10 minutes Dynamic Air Removal
- 270°F/132°C, 15 minutes Gravity
- 273°F/134°C, 4 minutes Dynamic Air Removal
- 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)

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Department of Health and Human Services
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
for
VERIFY STEAM INTEGRATING Indicator
K213412

Sponsor Facility
STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600

Manufacturing Facility
STERIS Franklin Park
11457 Melrose Ave.
Franklin Park, IL 60131
Phone: (847) 455-2881

Contact: Jennifer Nalepka, M.S.
Lead Regulatory Affairs Specialist
Phone: (440) 392-7458
Email: jennifer_nalepka@steris.com

Submission Date: January 18, 2022

Premarket Notification Number: K213412

1. Device Name

Trade Name:	VERIFY STEAM Integrating Indicator
Classification/usual Name:	Indicator, physical/chemical sterilization process
Device Classification:	II
Classification Name:	Indicator, physical/chemical sterilization process
Classification Number:	21 CFR 880.2800
Product Code:	JOJ

2. Predicate Device

VERIFY STEAM Integrating Indicator, K152630

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's 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/Indications for Use

The integrating indicator is designed to chemically react over time with the critical parameters of a 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, 5 minutes Dynamic Air Removal
- 270°F/132°C, 6 minutes Dynamic Air Removal
- 270°F/132°C, 7 minutes Dynamic Air Removal
- 270°F/132°C, 8 minutes Dynamic Air Removal
- 270°F/132°C, 9 minutes Dynamic Air Removal
- 270°F/132°C, 10 minutes Dynamic Air Removal
- 270°F/132°C, 15 minutes Gravity
- 273°F/134°C, 4 minutes Dynamic Air Removal
- 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. Summary of Technological Characteristics

A comparison of technical characteristics are summarized in **Table 1.**

Table 1. Summary of SCBI Physical Description and Technological Properties

Feature	VERIFY STEAM Integrating Indicator (K213412)	VERIFY STEAM Integrating Indicator (K152630)	Comparison
Intended Use	The integrating indicator is designed to chemically react over time with the critical parameters of a 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, 5 minutes Dynamic Air Removal • 270°F/132°C, 6 minutes Dynamic Air Removal • 270°F/132°C, 7 minutes Dynamic Air Removal • 270°F/132°C, 8 minutes Dynamic Air Removal • 270°F/132°C, 9 minutes Dynamic Air Removal • 270°F/132°C, 10 minutes Dynamic Air Removal • 270°F/132°C, 15 minutes Gravity	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	Similar, the proposed device has additional cycle claims.

Feature	VERIFY STEAM Integrating Indicator (K213412)	VERIFY STEAM Integrating Indicator (K152630)	Comparison
	• 273°F/134°C, 4 minutes Dynamic Air Removal • 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	• 275°F/135°C, 3 minutes Dynamic Air Removal • 275°F/135°C, 3 minutes Gravity • 275°F/135°C, 10 minutes Gravity	
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.	Identical
Indicator agent	Proprietary formulation	Proprietary formulation	Identical
Sterilization method and cycles	Steam Sterilization Cycles: • 250°F/121°C, 30 minutes Gravity • 270°F/132°C, 4 minutes Dynamic Air Removal • 270°F/132°C, 5 minutes Dynamic Air Removal • 270°F/132°C, 6 minutes Dynamic Air Removal • 270°F/132°C, 7 minutes Dynamic Air Removal • 270°F/132°C, 8 minutes Dynamic Air Removal • 270°F/132°C, 9 minutes Dynamic Air Removal • 270°F/132°C, 10 minutes Dynamic Air Removal	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	Similar, the proposed device has additional cycle claims.

Feature	VERIFY STEAM Integrating Indicator (K213412)	VERIFY STEAM Integrating Indicator (K152630)	Comparison
	• 270°F/132°C, 15 minutes Gravity • 273°F/134°C, 4 minutes Dynamic Air Removal • 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	• 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	
Mechanism of action	Proprietary	Proprietary	Identical
Endpoint specification	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 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.	Identical
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.	Identical
Shelf life	5 years	5 years	Identical
Standard/ Guidance	Conforms to: • Guidance for Industry and FDA Staff: Premarket	Conforms to: • Guidance for Industry and FDA Staff: Premarket	Identical

Feature	VERIFY STEAM Integrating Indicator (K213412)	VERIFY STEAM Integrating Indicator (K152630)	Comparison
	Notification [510(k)] Submissions for Chemical Indicators • ANSI/AAMI/ISO 11140-1:2014: Sterilization of Health Care Products – Chemical Indicators – Part 1: General Requirements	Notification [510(k)] Submissions for Chemical Indicators • ANSI/AAMI/ISO 11140-1:2014: Sterilization of Health Care Products – Chemical Indicators – Part 1: General Requirements	

6. Summary of Nonclinical Tests

Performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in **Table 2** below.

Table 2. Summary of nonclinical testing

Test	Acceptance Criteria	Conclusion
Simulated Use Testing in Claimed Sterilization Cycles	100% pass under pass conditions	**PASS**
	100% fail under fail conditions	**PASS**
Parallel performance as biological indicator	Integrator does not reach endpoint before the biological indicator is inactivated	**PASS**

7. Conclusion

Based on the intended use, technological characteristics and nonclinical performance data, the subject device (K213412) is as safe, as effective, and performs as well or better than the legally marketed predicate device (K152630), Class II (21 CFR 880.2800), product code JOJ.

510(k) Summary
for
VERIFY STEAM INTEGRATING Indicator 5CM

Sponsor Facility
STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600

Manufacturing Facility
STERIS Franklin Park
11457 Melrose Ave.
Franklin Park, IL 60131
Phone: (847) 455-2881

Contact: Jennifer Nalepka, M.S.
Lead Regulatory Affairs Specialist
Phone: (440) 392-7458
Email: jennifer_nalepka@steris.com

Submission Date: January 18, 2022

Premarket Notification Number: K213412

1. Device Name

Trade Name:	VERIFY STEAM Integrating Indicator 5CM
Classification/usual Name:	Indicator, physical/chemical sterilization process
Device Classification:	II
Classification Name:	Indicator, physical/chemical sterilization process
Classification Number:	21 CFR 880.2800
Product Code:	JOJ

2. Predicate Device

VERIFY STEAM Integrating Indicator - Short, K162631

3. Description of Device

The VERIFY STEAM Integrating Indicator 5CM is a single use device used by healthcare providers to monitor steam sterilization cycles. The VERIFY STEAM Integrating Indicator 5CM is included in a pack or load in a steam sterilizer and the load is processed in accordance with the sterilizer's 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/Indications for Use

The integrating indicator is designed to chemically react over time with the critical parameters of a 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, 5 minutes Dynamic Air Removal
- 270°F/132°C, 6 minutes Dynamic Air Removal
- 270°F/132°C, 7 minutes Dynamic Air Removal
- 270°F/132°C, 8 minutes Dynamic Air Removal
- 270°F/132°C, 9 minutes Dynamic Air Removal
- 270°F/132°C, 10 minutes Dynamic Air Removal
- 270°F/132°C, 15 minutes Gravity
- 273°F/134°C, 4 minutes Dynamic Air Removal
- 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. Summary of Technological Characteristics

A comparison of technical characteristics are summarized in **Table 1.**

Table 1. Summary of the Integrating Indicator Physical Description and Technological Properties

Feature	VERIFY STEAM Integrating Indicator 5CM (K213412)	VERIFY STEAM Integrating Indicator -Short (K162631)	Comparison
Intended Use	The integrating indicator is designed to chemically react over time with the critical parameters of a 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, 5 minutes Dynamic Air Removal • 270°F/132°C, 6 minutes Dynamic Air Removal • 270°F/132°C, 7 minutes Dynamic Air Removal • 270°F/132°C, 8 minutes Dynamic Air Removal • 270°F/132°C, 9 minutes Dynamic Air Removal • 270°F/132°C, 10 minutes Dynamic Air Removal	The integrating indicator is designed to chemically react over time with the critical parameters of a 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	Similar, the proposed device has additional cycle claims.

Feature	VERIFY STEAM Integrating Indicator 5CM (K213412)	VERIFY STEAM Integrating Indicator -Short (K162631)	Comparison
	• 270°F/132°C, 15 minutes Gravity • 273°F/134°C, 4 minutes Dynamic Air Removal • 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	• 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	
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.	Identical
Indicator agent	Proprietary formulation	Proprietary formulation	Identical
Sterilization method and cycles	Steam Sterilization Cycles: • 250°F/121°C, 30 minutes Gravity • 270°F/132°C, 4 minutes Dynamic Air Removal • 270°F/132°C, 5 minutes Dynamic Air Removal • 270°F/132°C, 6 minutes Dynamic Air Removal • 270°F/132°C, 7 minutes Dynamic Air Removal • 270°F/132°C, 8 minutes Dynamic Air Removal • 270°F/132°C, 9 minutes Dynamic Air Removal	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):	Similar, the proposed device has additional cycle claims.

Feature	VERIFY STEAM Integrating Indicator 5CM (K213412)	VERIFY STEAM Integrating Indicator -Short (K162631)	Comparison
	• 270°F/132°C, 10 minutes Dynamic Air Removal • 270°F/132°C, 15 minutes Gravity • 273°F/134°C, 4 minutes Dynamic Air Removal • 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	• 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	
Mechanism of action	Proprietary	Proprietary	Identical
Endpoint specification	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 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.	Identical
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.	Identical
Shelf life	3 years	3 years	Identical

Feature	VERIFY STEAM Integrating Indicator 5CM (K213412)	VERIFY STEAM Integrating Indicator -Short (K162631)	Comparison
Standard/ Guidance	Conforms to: • Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators • ANSI/AAMI/ISO 11140-1:2014: Sterilization of Health Care Products – Chemical Indicators – Part 1: General Requirements	Conforms to: • Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators • ANSI/AAMI/ISO 11140-1:2014: Sterilization of Health Care Products – Chemical Indicators – Part 1: General Requirements	Identical

6. Summary of Nonclinical Tests

Performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in **Table 2** below.

Table 2. Summary of nonclinical testing

Test	Acceptance Criteria	Conclusion
Simulated Use Testing in Claimed Sterilization Cycles	100% pass under pass conditions	**PASS**
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Parallel performance as biological indicator	Integrator does not reach endpoint before the biological indicator is inactivated	**PASS**

7. Conclusion

Based on the intended use, technological characteristics and nonclinical performance data, the subject device (K213412) is as safe, as effective, and performs as well or better than the legally marketed predicate device (K162631), Class II (21 CFR 880.2800), product code JOJ.