DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 21, 2017

STERIS Corporation
Mr. Anthony Piotrkowski
Senior Manager, Regulatory Affairs
5960 Heisley Rd.
Mentor, Ohio 44060

Re: K162758
Trade/Device Name: VERIFY® Steam Indicators (VERIFY® SixCess® Chemical Indicators)
VERIFY 275F 3 Indicators (VERIFY® SixCess Indicators)
VERIFY 275F Gravity Indicators (VERIFY® SixCess Indicators)
VERIFY Challenge Packs - Version 2 (VERIFY® SixCess Challenge Pack)
VERIFY 270FP Challenge Pack
Browne TST Dual Use Test Pack (VERIFY® Bowie Dick Test Pack)
Regulation Number: 21 CFR 880.2800(b)
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: February 15, 2017
Received: February 16, 2017

Dear Mr. Anthony 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting 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)*
K162758

Device Name
VERIFY® Steam Indicators (VERIFY® SixCess® Chemical Indicators)

Indications for Use *(Describe)*

The Verify® Steam Indicators are emulating indicators intended for use in steam sterilization. The Verify® Steam Indicators change color from yellow to blue/purple when exposed to the appropriate cycle temperature, type, and duration. The indicator models and their cycle temperatures, types, and times are:

MODEL	TEMPERATURE	STERILIZATION TYPE	TIME
Verify 250F 30	250ºF (121ºC)	gravity steam	30 minutes
Verify 270F 15	270ºF (132ºC)	gravity steam	15 minutes
Verify 270F 3-10	270ºF (132ºC)	gravity flash steam	3 or 10 minutes
Verify 270F 4	270ºF (132ºC)	SFPP, pre-vacuum and Express steam	4 minutes

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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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162758

Device Name
VERIFY 275F 3 Indicator (VERIFY® SixCess Indicators)

Indications for Use *(Describe)*

The Verify® 275F 3 Indicator is a chemical indicator intended for use by health care providers to accompany products being sterilized through a sterilization procedure. The Verify® 275F 3 Indicator is an emulating indicator intended for use in steam sterilization. The indicator changes color from yellow to blue/purple when exposed to 275ºF (135ºC) pre-vacuum sterilization cycles for 3 minutes as indicated in the following table:

MODEL	TEMPERATURE	STERILIZATION TYPE	TIME
Verify 275F 3	275ºF (135ºC)	Pre-vacuum steam	3 minutes

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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Indications for Use

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Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162758

Device Name
VERIFY 275F Gravity Indicators (VERIFY® SixCess Indicators)

Indications for Use *(Describe)*

The Verify® 275F Gravity Indicators are chemical integrators which meet ANSI/AAMI 1140-1:2005 for emulating indicators intended for use in steam sterilization. The Verify® 275F Gravity Indicators change color from yellow to blue/ purple when exposed to 275ºF (135ºC) and to the appropriate cycle type and duration. The Verify® 275F Indicators models and their cycle types and times are:

MODEL	TEMPERATURE	STERILIZATION TYPE	TIME
Verify 275F 3-10	275ºF (135ºC)	Gravity flash steam	3 and 10 minutes
Verify 275F 10	275ºF (135ºC)	Gravity steam	10 minutes

Type of Use *(Select one or both, as applicable)*

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Indications for Use

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Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162758

Device Name
VERIFY Challenge Packs - Version 2 (VERIFY® SixCess Challenge Pack)

Indications for Use *(Describe)*

The Verify® Challenge Packs –Version 2 - are test packs consisting of an emulating indicator surrounded by a steam penetration barrier, intended for use in steam sterilization. The Verify® Challenge Packs indicators change color from yellow to blue/purple when exposed to the appropriate cycle temperature, type, and duration. The challenge pack models and their cycle temperatures, types, and times are:

- Verify® 270F 4 - 270ºF (132ºC) Pre-vacuum, Steam Flush Pressure Pulse (SFPP), 4 minutes
- Verify® 275F 3 - 275ºF (135ºC) Pre-vacuum 3 minutes

There is a process indicator outside of the packs which undergoes a visual color change when exposed to steam in a temperature range of 250ºF (121ºC) to 275ºF (135ºC).

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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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162758

Device Name
VERIFY 270FP Challenge Pack

Indications for Use *(Describe)*

The Verify® 270FP Challenge Pack is a test pack consisting of three emulating indicator inks situated on a test sheet surrounded by a steam penetration barrier, intended for use in SFPP (steam-flush pressure-pulse) and pre-vacuum steam sterilization for load release. The Verify® 270FP Challenge Pack indicators change color from yellow to blue/purple when exposed to the following conditions at 270 F (132C):

- 4 minute indicator - SFPP and pre-vacuum steam sterilization for 4 minutes.
- 10 minute indicator - Pre-vacuum steam sterilization for 10 minutes.
- 20 minute indicator - Pre-vacuum steam sterilization for 20 minutes.

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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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)*
K162758

Device Name
Browne TST Dual Use Test Pack (VERIFY® Bowie Dick Test Pack)

Indications for Use *(Describe)*

The Browne TST Dual Use Test Pack is a chemical sterilization process monitor that can be used as either:

- Bowie Dick Test - in an empty chamber to monitor air removal and steam penetration during the vacuum stage of 132ºC (270ºF) , 134ºC (273ºF) , and 135 ºC (275 ºF) test cycles.

- Challenge Pack - in a loaded chamber to monitor steam penetration during the hold/plateau stage of 132ºC (270ºF), 134 ºC (273 ºF), and 135 ºC (275 ºF) steam sterilization cycles.

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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510(k) Summary
For
K162758 VERIFY® SixCess® Chemical Indicators
and
Chemical Indicator Challenge Packs

STERIS Corporation
5960 Heisley Road
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Phone: (440) 354-2600
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Contact: Anthony Piotrkowski
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Submission Date: March 20, 2017

Premarket Notification Number: K162758

1. Device Name

Trade Name: VERIFY® Steam Indicators (VERIFY® SixCess® Chemical Indicators)
VERIFY 275F 3 Indicators (VERIFY® SixCess Indicators)
VERIFY 275F Gravity Indicators (VERIFY® SixCess Indicators) VERIFY Challenge Packs - Version 2 (VERIFY® SixCess Challenge Pack)
VERIFY 270FP Challenge Pack
Browne TST Dual Use Test Pack (VERIFY® Bowie Dick Test Pack)

Device Class:	Class II
Common/usual Name:	Chemical Indicator
Classification Name:	Physical/chemical sterilization process indicators
Classification Number:	21 CFR 880.2800 (b)
Product Code:	JOJ

2. Predicate Devices

510(k) #	Device Name
K002741	Browne TST Dual Use Test Pack
K070461	VERIFY Steam Indicators
K071895	VERIFY 275F 3 Indicator
K073683	VERIFY Challenge Packs – Versions 2
K083643	VERIFY 275F Gravity Indicator
K103053	VERIFY 270FP Challenge Pack

The proposed devices are identical to the predicates in performance and composition with the following exceptions:

- Solvent is changing to a REACh compliant base – the solvent evaporates during the printing process.
- Plasticizer is changing to a REACh compliant chemical – the plasticizer is an inert component and makes the ink easier to work with during the printing process.
- Adhesive is changing to a REACh compliant chemical – the adhesive is inert and used to adhere laminate to substrate.
- Labeling references the (most recent) 2014 revision of ISO 11140-1 and uses the newly introduced “Type 6” in place of “Class 6”.

3. Description of Device

3.1 The VERIFY® SixCess Chemical Indicators consist of a 22mm x 143 mm strip (long) (7/8" x 5.6") or a 22mm X 70 mm (short) polypropylene strip with a 12 mm circular chemical indicator ink spot (or two spots in the case of the 270ºF 3-10 Indicator) located on one end, adjacent to a reference circle exhibiting the endpoint color. The indicator ink on the proposed VERIFY® Steam Indicators change from yellow to blue/purple color when the steam sterilization cycle is complete.

- The Verify® 250ºF 30 Indicator (models: PCC005, *VERIFY SixCess 250F 30 Minute Indicator – Short*, and PCC007, *VERIFY SixCess 250F 30 Minute Indicator - Long*) can be used to monitor a 30 minute 250ºF/121ºC gravity steam sterilization cycle.
- The Verify® 270ºF 15 Indicator (model PCC031, *VERIFY SixCess 270F 15 Minute Indicator*) can be used to monitor a 15 minute 270ºF/132ºC gravity steam sterilization cycle.
- The Verify® 270ºF 3-10 Indicator (model LCC310, *VERIFY SixCess 270F Flash Indicator*) can be used to monitor a 3 minute or10 minute 270ºF/132ºC gravity flash steam sterilization cycle.
- The Verify® 270ºF 4 Indicator (models PCC006, *VERIFY SixCess 270F 4 Minute Indicator - Short* and PCC008, *VERIFY SixCess 270F 4 Minute Indicator - Long*) can be used to monitor a 4 minute 270ºF/132ºC SFPP, pre-vacuum and Express steam sterilization cycle.

3.2 The Verify® 275F Indicator consist of:

- A 22 mm x 143 mm (long) or a 22mm X 70 mm (short) polypropylene strip with one 12 mm chemical indicator ink spot.

The indicator ink spots are located on each end of the strip (or one end if it is just one ink spot), adjacent to a reference block exhibiting the endpoint color. The indicator ink on the proposed Verify® 275F Indicator changes from yellow to blue/purple color when the steam sterilization cycle is complete.

The Verify® 275F Indicator can be used to monitor 275ºF (135ºC) sterilization cycles as follows:

- The Verify® 275F 3 Indicator (models PCC034, *VERIFY SixCess 275F 3 Minute Indicator - Long* and PCC038, *VERIFY SixCess 275F 3 Minute Indicator – Short)* can be used to monitor a 3 minute 275ºF (135ºC) pre-vacuum steam sterilization cycle.

3.3 The Verify® 275F Gravity Indicators consist of:

- A 22 mm x 143 mm polypropylene strip with two 12 mm chemical indicator ink spots (for Verify® 275F 3-10 Indicator).
- A 22 mm x 143 mm (long) or a or a 22mm X 70 mm (short) polypropylene strip with one 12 mm chemical indicator ink spots (for Verify® 275F 10 Indicator).

The indicator ink spots are located on each end of the strip (or one end if it is just one ink spot), adjacent to a reference block exhibiting the endpoint color. The indicator ink on the proposed Verify® 275F Gravity Indicators changes from yellow to blue/purple color when the steam sterilization cycle is complete.

The Verify® 275F Gravity Indicators can be used to monitor 275ºF (135ºC) sterilization cycles as follows:

- The Verify® 275F 3-10 Indicator (model LCC005, *VERIFY SixCess 275F Flash Indicator*) can be used to monitor a 3 and 10 minute 275ºF (135ºC) gravity flash steam sterilization cycle (including prevacuum, single wrapped trays).
- The Verify® 275F 10 Indicator can be used to monitor a 10 minute 275ºF (135ºC) gravity steam sterilization cycle.

3.4 The VERIFY® Challenge Packs – Version 2 consists of an emulating indicator surrounded by a steam penetration barrier. The indicator ink inside the proposed Verify® Challenge Packs changes from yellow to blue/purple color when the steam sterilization cycle is complete:

- The Verify® 270F 4 Challenge Pack –Version 2 (model LCC003, *VERIFY SixCess 270F 4 Challenge Pack*) - can be used to monitor a 4 minute 270ºF/132ºC Steam-Flush Pressure-Pulse (SFPP) and pre-vacuum steam sterilization cycle.
- The Verify® 275F 3 Challenge Pack – Version 2 – (model LCC014, *VERIFY SixCess 275F 3 Challenge Pack)* can be used to monitor a 3 minute 275ºF/135ºC pre-vacuum steam sterilization cycle.

The process indicator outside of the packs undergoes a visual color change from pink to dark purple when exposed to steam in a temperature range of 250ºF (121ºC) to 275ºF (135ºC).

3.5 The *VERIFY® 270FP Challenge Pack*, Model LCC019, consists of three emulating indicator inks situated on a test sheet surrounded by a steam penetration barrier. The indicator inks on the proposed Verify® 270FP Challenge Pack test sheet change from yellow to blue/purple color when exposed to saturated steam at 270°F (132°C) for the following times.

- 4 minute indicator – The 4 minute indicator ink on the Verify® 270FP Challenge Pack can be used to monitor a 4 minute SFPP (steam-flush pressure-pulse) and pre-vacuum steam sterilization cycle.
- 10 minute indicator – The 10 minute indicator ink on the Verify® 270FP Challenge Pack can be used to monitor a 10 minute pre-vacuum steam sterilization cycle.
- 20 minute indicator – The 20 minute indicator ink on the Verify® 270FP Challenge Pack can be used to monitor a 20 minute pre-vacuum steam sterilization cycle.

The process indicator outside of the packs undergoes a visual color change from pink to dark purple when exposed to steam in a temperature range of 250°F (121°C) to 275°F (135°C).

3.6 The TST Test Pack (models EQC009 and EQC010, *VERIFY Bowie Dick Test Pack*) consists of a chemical integrator surrounded by a steam penetration barrier. The indicator ink used for the Integrator Test Pack integrator is identical to the ink used for the TST Control Integrator for Steam Autoclave (K965154).

4. Intended Use

4.1 Verify® Steam Indicators

The Verify® Steam Indicators are emulating indicators intended for use in steam sterilization. The Verify® Steam Indicators change color from yellow to blue/purple when exposed to the appropriate cycle temperature, type, and duration. The indicator models and their cycle temperatures, types, and times are:

MODEL	TEMPERATURE	STERILIZATION TYPE	TIME
Verify 250F 30	250ºF (121ºC)	gravity steam	30 minutes
Verify 270F 15	270ºF (132ºC)	gravity steam	15 minutes
Verify 270F 3-10	270ºF (132ºC)	gravity flash steam	3 or 10 minutes
Verify 270F 4	270ºF (132ºC)	Steam Flush Pressure Pulse (SFPP), pre-vacuum and Express steam	4 minutes

4.2 Verify® 275F 3 Indicator

The Verify® 275F 3 Indicator is a chemical indicator intended for use by health care providers to accompany products being sterilized through a sterilization procedure. The Verify® 275F 3 Indicator is an emulating indicator intended for use in steam sterilization. The indicator changes color from yellow to blue/purple when exposed to 275ºF (135ºC) pre-vacuum sterilization cycles for 3 minutes as indicated in the following table:

MODEL	TEMPERATURE	STERILIZATION TYPE	TIME
Verify 275F 3	275ºF (135ºC)	Pre-vacuum steam	3 minutes

4.3 Verify® 275F Gravity Indicators

The Verify® 275F Gravity Indicators are chemical integrators which meet ANSI/AAMI 1140-1:2005 for emulating indicators intended for use in steam sterilization. The Verify® 275F Gravity Indicators change color from yellow to blue/purple when exposed to 275ºF (135ºC) and to the appropriate cycle type and duration. The Verify® 275F Indicators models and their cycle types and times are:

MODEL	TEMPERATURE	STERILIZATION TYPE	TIME
Verify 275F 3-10	275ºF (135ºC)	Gravity flash steam	3 and 10 minutes
Verify 275F 10	275ºF (135ºC)	Gravity steam	10 minutes

4.4 Verify® Challenge Packs

The Verify® Challenge Packs –Version 2 - are test packs consisting of an emulating indicator surrounded by a steam penetration barrier, intended for use in steam sterilization. The Verify® Challenge Packs indicators change color from yellow to blue/purple when exposed to the appropriate cycle temperature, type, and duration. The challenge pack models and their cycle temperatures, types, and times are:

MODEL	TEMPERATURE	STERILIZATION TYPE	TIME
Verify® 270F 4	270ºF (132ºC)	Pre-vacuum, Steam Flush Pressure Pulse (SFPP)	4 minutes
Verify® 275F 3	275ºF (135ºC)	Pre-vacuum	3 minutes

There is a process indicator outside of the packs which undergoes a visual color change when exposed to steam in a temperature range of 250ºF (121ºC) to 275ºF (135ºC).

4.5 Verify® 270FP Challenge Pack

The Verify® 270FP Challenge Pack is a test pack consisting of three emulating indicator inks situated on a test sheet surrounded by a steam penetration barrier, intended for use in SFPP (steam-flush pressure-pulse) and pre-vacuum steam sterilization for load release. The Verify® 270FP Challenge Pack indicators change color from yellow to blue/purple when exposed to the following conditions at 270ºF (132ºC):

- 4 minute indicator - SFPP and pre-vacuum steam sterilization for 4 minutes.
- 10 minute indicator - Pre-vacuum steam sterilization for 10 minutes.
- 20 minute indicator - Pre-vacuum steam sterilization for 20 minutes.

4.6 TST Dual Use Test Pack

The Browne TST Dual Use Test Pack is a chemical sterilization process monitor that can be used as either:

- Bowie Dick Test - in an empty chamber to monitor air removal and steam penetration during the vacuum stage of 132ºC (270ºF), 134ºC (273ºF), and 135 ºC (275 ºF) test cycles.

- Challenge Pack - in a loaded chamber to monitor steam penetration during the hold/plateau stage of 132ºC (270ºF), 134 ºC (273 ºF), and 135 ºC (275 ºF) steam sterilization cycles.

5. Description of Safety and Substantial Equivalence

5.1 Technology Comparison

- Features – identical between predicate and proposed device
- Principle of operation – identical between predicate and proposed devices
- Types/models – identical between predicate and proposed devices
- Materials - identical between predicate and proposed devices with the exception of the three ink formulation changes described in section 2 above.

Feature	Predicate	Proposed	Comparison
Substrate	Polypropylene	Polypropylene	Same
Ink	Proprietary	Identical formulation as predicate with exception of inert components - solvent, plasticizer and adhesive	Data presented in the submission to demonstrate similarities
Performance Specification (Type 6)	Meets ISO 11140 requirements for Type 6 indicator	Meets ISO 11140 requirements for Type 6 indicator	Same
Performance Specification (BD)	Meets ISO 11140 requirements for Bowie Dick indicator	Meets ISO 11140 requirements for Bowie Dick indicator	Same
Intended Use	No change to intended use or indications for use between proposed and predicate		Same
Mechanism of Action	No change to mechanism of action between proposed and predicate		Same

5.2 Effectiveness Comparison

The ink formulation changes were to inert component of the chemical indicator ink. The testing described in the table below, over the 3-year shelf-life, demonstrated equivalent performance of the proposed indicators to the predicates.

Test	Predicate	Proposed	Comparison
Performance in a sterilizer	Pass	Pass	Same
Performance in a resistometer	Pass	Pass	Same
No delamination of indicators following exposure to steam	Pass	Pass	Same

5.3 Safety Comparison

The ink formulation changes were to inert component of the chemical indicator ink, and the further the solvent is not present in the final product. The safety of the indicator products is inherent to their design. Indicators are not intended to contact patients. All indicators are laminated to prevent contact of the indicator ink with items within a sterilization load. Challenge pack indicators are further contained within steam barrier materials.

6. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the subject devices are substantially equivalent and is as safe and as effective as the legally marketed predicate device Class II (21 CFR 880.2800, Product code JOJ).