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

April 21, 2017

Sybron Dental Specialties
Jennifer Dzidrums
Regulatory Affairs Associate Ii
1717 W. Collins Ave.
Orange, California 92867

Re: K162063
Trade/Device Name: Steri-Cassette and Steri-Cage Sterilization Packaging System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: March 15, 2017
Received: March 20, 2017

Dear Jennifer Dzidrums:

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" (21 CFR 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)*

K162063

Device Name

Steri-Cassette and Steri-Cage Sterilization Packaging Systems

Indications for Use *(Describe)*

The Steri-Cassettes and Steri-Cages are intended to contain dental instruments for cleaning, sterilization, organization, storage and handling. The Steri-Cassettes and Steri-Cages are suitable for pre-vacuum and gravity displacement steam sterilization methods. The cassettes and cages are not intended to maintain sterility; they are intended to be used in conjunction with validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices.

The validated steam sterilization cycle parameters are as follows:

Steam Sterilization Cycle	Minimum Exposure Temperature	Minimum Exposure Time	Minimum Dry Time
Gravity Displacement (wrapped)	250°F (121°C)	30 Minutes	15 Minutes
Gravity Displacement (wrapped)	270°F (132°C)	15 Minutes	15 Minutes
Gravity Displacement (wrapped)	275°F (135°C)	10 Minutes	30 Minutes
Gravity Displacement **(unwrapped for immediate use)**	132°C (270°F)	3 Minutes	None
Pre-Vacuum (wrapped)	270°F (132°C)	4 Minutes	30 Minutes
Pre-Vacuum (wrapped)	275°F (135°C)	3 Minutes	16 Minutes
Pre-Vacuum **(unwrapped for immediate use)**	273°F (134°C)	3 Minutes	None

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.

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510(k) SUMMARY for Steri-Cassette and Steri-Cage

K162063

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Applicant Information:

Sybron Dental Specialties
1717 W. Collins Ave.
Orange CA, 92687 USA
Fax: 909-962-5694

Correspondent Contact Information:

Jennifer Dzidrums, MS, RAC
Regulatory Affairs Associate II
Tel: 909-962-5650
Fax: 909-962-5694

Date Prepared: April 17, 2017

B. Subject Device:

Trade Name	*Steri-Cassette and Steri-Cage* Sterilization Packaging System
Classification Name	Sterilization wrap containers, trays, cassettes & other accessory
Regulation Number	21 CFR § 880.6850
Common Name	Instrument Cassette, Sterilization Cassette
Device Class	II
Product Code	KCT
Panel	General Hospital

C. Predicate Device:

Trade Name	PolyVac Surgical Instrument Delivery System's *Instrument Cassettes*
510(k) Holder	Symmetry Medical, Inc. (previously PolyVac, Inc.)
510(k) #	K012105 (FDA-cleared on August 02, 2002)
Classification Name	Sterilization wrap containers, trays, cassettes & other accessory
Regulation Number	21 CFR § 880.6850
Common Name	Instrument Cassette/ Tray, Sterilization Cassette/ Tray
Device Class	II
Product Code	KCT
Panel	General Hospital

D. Description of Device:

Steri-Cassettes and Steri-Cages are used to hold instruments in a secure way for cleaning, sterilization and presentation at point of use. They keep instrumentation organized in an efficient way. They are available in a variety of sizes to accommodate instruments of various sizes and are offered in an assortment of colors to aid in office organization.

Design

Steri-Cassettes and Steri-Cages have perforations consisting of open-slots on the lid and the base which allows exposure of the device to the sterilant during sterilization. All the five variations of the stackable Steri-Cassettes and Steri-Cages have the same design of open-slot perforations on their lid and base (1) Steri-Cassette AA – Shallow – High Heat, (2) Steri-Cassette AA – Shallow – Standard Heat, (3) Steri-Cassette AB – Medium – High Heat, (4) Steri-Cassette BB – Deep – High Heat and (5) Steri-Cage – Standard Heat. Steri-Cassettes include instrument holder inserts, which are removable and individually hold instruments. Refer to Table **5.1** for the various colors, measurements, construction and heat resistance for these hinged sterilization cassettes and cages. Standard Heat Steri-Cassettes and Steri-Cages and High Heat Steri-Cassettes can withstand 275°F and 320°F per performance and Sterilization Validation testing, and resin specifications).

Since the proposed devices are perforated, an FDA-cleared sterilization wrap must be used to maintain sterility of its contents. The evenly–spaced open slots are sufficient to support sterilant penetration and drying as per ANSI/AAMI ST 77.

Composition and Manufacturing Process

Cassettes and cages are manufactured by Injection Molding process from either high-heat resin or polypropylene with color – materials widely used in the medical field. The colors are already pre-mixed and vary by color in the supplier's proprietary resin mixtures: Steri-Cassettes High-Heat: RoHs-compliant, high-heat resin - Ultem Resin 1000 and Steri-Cassettes Standard Heat and Steri-Cages: polypropylene with color. The manufacturer name and UDI direct part marking will be added to the mold during the Injection Molding process.

The cassettes and cage have a latching lid to contain the products. The proposed devices are designed to fit any standard autoclave and ultrasonic machine (**Table 5.1**), which allows it to be effective for sterilization and be able to withstand the environment of repeated steam sterilization cycles. Since the proposed cassettes and cages have open slots, a legally-marketed and FDA-cleared sterilization wrap must be used for sterilization purposes to maintain the sterility of the contents.

The proposed Steri-Cassettes and Steri-Cages are packaged in non-sterile, plastic shrink-wrap, which is then appropriately labeled and includes a validated Cleaning and Sterilization/ Dry Time Instructions for use.

Table 5.2 describes the validated, FDA-cleared sterilization pouch required for the sterilization procedure.

Table 5.1: Design Description: Subject Device – Size, Color and Heat-Resistance Type

Note: Coordinating PeelVue+ size and shape identified by Part Number.

Proposed Device Name and Heat-Resistance	**Part Number**	**PeelVue+ Part Number**	**Color**	**Outer Dimensions** (when closed) Width x Depth x Height
Steri-Cassette AA – Shallow – High Heat	31591	31615	Beige	7.5" x 5.5" x 1.5"
Steri-Cassette AA – Shallow – Standard Heat	32520, 32521, 32522, 32523, 32524, 32525	31615	French Vanilla, Sand, Light Mauve, Seafoam, Lilac, Baby Blue	
Steri-Cassette AB – Medium – High Heat	31592	Baby Blue 31643 or Forest Green 31647	Beige	7.5" x 5.5" x 2.25"
Steri-Cassette BB – Deep – High Heat	31593	Baby Blue 31643 or Forest Green 31647	Beige	7.5" x 5.5" x 3.0"
Steri-Cage – Standard Heat	32506, 32507, 32508, 32509, 32510, 32511, 32512, 32513, 32514	31645 31615	French Vanilla, Sand, Light Mauve, Seafoam, Lilac, Baby Blue, White, Gray, Beige	8.00" x 1.75" x 1.75"

Table 5.2: Recommended System Components – Used in Conjunctions with Subject Devices

Description and Specific Recommendation	FDA Clearance Information	Manufacturer
Validated, FDA-cleared sterilization pouch – PeelVue+ sterilization pouches recommended*	• 510(k) #: K894437 • Product Code: FRG • Regulation #: 21 CFR § 880.6850 • Class: II	Kerr Corporation 1717 W. Collins Ave. Orange, CA 92867 USA Establishment Registration: 2024312

**Specific brand used in Sterilization Validation testing for the subject devices.*

E. Statement of Indications for Use:

The Steri-Cassettes and Steri-Cages are intended to contain dental instruments for cleaning, sterilization, organization, storage and handling. The Steri-Cassettes and Steri-Cages are suitable for pre-vacuum and gravity displacement steam sterilization methods. The cassettes and cages are not intended to maintain sterility; they are intended to be used in conjunction with validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices.

The validated steam sterilization cycle parameters are as follows:

Steam Sterilization Cycle	Minimum Exposure Temperature	Minimum Exposure Time	Minimum Dry Time
Gravity Displacement (wrapped)	250°F (121°C)	30 Minutes	15 Minutes
Gravity Displacement (wrapped)	270°F (132°C)	15 Minutes	15 Minutes
Gravity Displacement (wrapped)	275°F (135°C)	10 Minutes	30 Minutes
Gravity Displacement **(unwrapped for immediate use)**	132°C (270°F)	3 Minutes	None
Pre-Vacuum (wrapped)	270°F (132°C)	4 Minutes	30 Minutes
Pre-Vacuum (wrapped)	275°F (135°C)	3 Minutes	16 Minutes
Pre-Vacuum **(unwrapped for**	273°F (134°C)	3 Minutes	None

immediate use)			

Table 5.3: Device Comparison Table Demonstrating Substantial Equivalence

Element	**Subject Device** *Steri-Cassette and Steri-Cage*	**Predicate Device (K012105)** PolyVac Surgical Instrument Delivery System's *Instrument Cassettes*	**Subject Device** **vs.** **Predicate Device**
Trade/ Proprietary Name	*Steri-Cassette and Steri-Cage* Sterilization Packaging System	PolyVac Surgical Instrument Delivery System's *Instrument Cassettes*	N/A
Fundamental Scientific Technology	Sterilization Cassette	Sterilization Cassette	Same
Product Code, Regulation No. and Device Class	KCT (21 CFR § 880.6850), Class II	KCT (21 CFR § 880.6850), Class II	Same
Legal Manufacturer	Kerr Corporation 1717 W. Collins Ave. Orange, CA 92867 USA Registration Number: 2024312	Symmetry Medical, Inc. (previously PolyVac, Inc.) 220 West Market Street Warsaw, Indiana 46582 USA Registration Number: Not stated in predicate's 510(k) summary	N/A
Contract Manufacturer	SDS de Mexico S. de R.L. de C.V. *(subsidiary of Kerr)* Circuito Sur Num. 31 Parque Ind. Nelson Mexicali, B.C. C.P. Baja California, MEXICO 21395 Registration Number: 9680845	Not stated in predicate's 510(k) summary	N/A
Intended Use	Perforated trays with lids to hold surgical instruments in place during transport, steam sterilization, and storage	Perforated trays with lids to hold surgical instruments in place during transport, steam sterilization, and storage	Same

Element	**Subject Device** *Steri-Cassette and Steri-Cage*	**Predicate Device (K012105)** PolyVac Surgical Instrument Delivery System's *Instrument Cassettes*	**Subject Device** **vs.** **Predicate Device**
Description	Steri-Cassettes and Steri-Cages are used to hold instruments in a secure way for cleaning, sterilization and presentation at point of use. They keep instrumentation organized in an efficient way. They are available in a variety of sizes to accommodate instruments of various sizes and are offered in an assortment of colors to aid in office organization.	PolyVac Delivery Systems consist of different sizes of the same basic configuration. All systems consist of a minimum of a plastic or metal base and lid. All lids can be fastened to the base by means of assembled hardware or by a locking tab, designed as part of the lid. Accessories may be used with systems to organize or separate contents to be placed in them for use. The Delivery Systems are designed using plastic and metal materials that can be reused with steam sterilization methods. Each tray and lid has an evenly distributed hole pattern in relation to its size.	Similar

<table>
<tr><th>Element</th><th>Subject Device
Steri-Cassette and Steri-Cage</th><th>Predicate Device (K012105)
PolyVac Surgical Instrument Delivery System’s
Instrument Cassettes</th><th>Subject Device
vs.
Predicate Device</th></tr>
<tr><td>Indications for Use</td><td>The Steri-Cassettes and Steri-Cages are intended to contain dental instruments for cleaning, sterilization, organization, storage and handling. The Steri-Cassettes and Steri-Cages are suitable for pre-vacuum and gravity displacement steam sterilization methods. The cassettes and cages are not intended to maintain sterility; they are intended to be used in conjunction with validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices.

The validated steam sterilization cycle parameters are as follows:
<table>
<tr><th>Steam Sterilization Cycle</th><th>Minimum Exposure Temperature</th><th>Minimum Exposure Time</th><th>Minimum Dry Time</th></tr>
<tr><td>Gravity Displacement (wrapped)</td><td>250°F (121°C)</td><td>30 Minutes</td><td>15 Minutes</td></tr>
<tr><td>Gravity Displacement (wrapped)</td><td>270°F (132°C)</td><td>15 Minutes</td><td>15 Minutes</td></tr>
<tr><td>Gravity Displacement (wrapped)</td><td>275°F (135°C)</td><td>10 Minutes</td><td>30 Minutes</td></tr>
<tr><td>Gravity Displacement (unwrapped for immediate use)</td><td>132°C (270°F)</td><td>3 Minutes</td><td>None</td></tr>
<tr><td>Pre-Vacuum (wrapped)</td><td>270°F (132°C)</td><td>4 Minutes</td><td>30 Minutes</td></tr>
<tr><td>Pre-Vacuum (wrapped)</td><td>275°F (135°C)</td><td>3 Minutes</td><td>10 Minutes</td></tr>
<tr><td>Pre-Vacuum</td><td></td><td></td><td></td></tr>
</table></td><td>PolyVac's delivery systems consist of perforated trays with lids, which are intended to enclose and protect medical device instrumentation, and to facilitate the sterilization process by allowing steam penetration and air removal. When used in conjunction with an approved sterilization wrap, sterility of the enclosed medical device is maintained until used.
PolyVac's delivery systems are to be sterilized in one of the following cycles:
Prevacuum Steam: 132°C - 4 minutes minimum
Gravity Steam: 132°C - 30 minutes minimum
Gravity Steam: 121°C - 55 minutes minimum</td><td>Similar</td></tr>
</table>

Element	**Subject Device** *Steri-Cassette and Steri-Cage*	**Predicate Device (K012105)** PolyVac Surgical Instrument Delivery System's *Instrument Cassettes*	**Subject Device** **vs.** **Predicate Device**
		– DESIGN –	
Material Composition	Cassettes – High Heat: High-Resistant Plastic - Ultem Resin 1000 (proprietary mixture with pigments) (*thermoplastic*) Cassettes – Standard Heat: polypropylene with color (proprietary mixture with pigments) (*thermoplastic*) Cages: polypropylene with color (proprietary mixture with pigments) (*thermoplastic*)	Trays & Lids: Aluminum, 300 Series stainless steel, biomedical grade silicone; or Radal R Plastic **Instrument Cassettes:** Radal R Plastic (*thermoplastic*)	Similar
Design/ Configuration	Cassettes and cages are manufactured from one of two thermoplastic mixtures used in injection molding. Perforated (slotted) base and lid hinge together and are secured with a latch mechanism (tab on lid). Cassettes have built-in inserts used to stabilize the instruments. These inserts are removable and composed of the same thermoplastic as the body of the cassette. Cassettes and cages are stackable.	**Instrument Cassettes**: Manufactured from a thermoplastic mixture (Radal R) used in injection molding. Perforated (slots and holes) base and lid hinge together and are secured with a latch mechanism (tab on lid). Cassettes have built-in slots (Radal R) used to stabilize the instruments or may use a non-slip, silicone mat to secure the instruments while providing ventilation to facilitate drying. Cassettes are stackable.	Similar
Manufacturing Process	Injection Molding	Injection Molding	Same

<table>
<tr><th>Element</th><th>Subject Device
Steri-Cassette and Steri-Cage</th><th>Predicate Device (K012105)
PolyVac Surgical Instrument Delivery System’s
Instrument Cassettes</th><th>Subject Device
vs.
Predicate Device</th></tr>
<tr><td>Dimensions</td><td>Various – refer to Table 5.1 for outer dimensions</td><td>Various depending on model of Instrument Cassette:
<table>
<tr><th>Device Name</th><th>Part Number</th><th>Outer Dimensions (when closed) Width x Depth x Height</th></tr>
<tr><td>Shallow Cassette w/ Silicone Mat</td><td>7-6050</td><td>8.0” x 4.5” x 0.61”</td></tr>
<tr><td>Deep Cassette w/ Silicone Mat</td><td>7-1250</td><td>8.0” x 4.5” x 1.2”</td></tr>
<tr><td>6-Position Slots</td><td>7-6000</td><td>8.0” x 4.5” x 0.61”</td></tr>
<tr><td>12-Position Slots</td><td>7-1200</td><td>8.0” x 4.5” x 0.61”</td></tr>
</table></td><td>Similar</td></tr>
<tr><td>Air Permeance</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td>Percent Perforation</td><td>Each base and lid contains evenly distributed slot-pattern in relation to its size.</td><td>Each base and lid contains evenly distributed slot and hole pattern in relation to its size.</td><td>Same</td></tr>
<tr><td colspan="4">– PERFORMANCE CHARACTERISTICS and VALIDATION TESTING –</td></tr>
<tr><td>Cleaning Instructions for Reusable Devices</td><td>Yes – Per Cleaning Validations conducted.</td><td>Yes – Per Cleaning Validations conducted.</td><td>Same</td></tr>
<tr><td>Sterilization Method</td><td>• Pre-Vacuum
• Gravity Displacement</td><td>• Pre-Vacuum
• Gravity Displacement</td><td>Same</td></tr>
</table>

<table>
<tr><th>Element</th><th>Subject Device
Steri-Cassette and Steri-Cage</th><th>Predicate Device (K012105)
PolyVac Surgical Instrument Delivery System’s
Instrument Cassettes</th><th>Subject Device
vs.
Predicate Device</th></tr>
<tr><td>Sterilization Parameters per US Requirements (wrapped)*</td><td>
<table>
<tr><th>Steam Sterilization Cycle</th><th>Minimum Exposure Temperature</th><th>Minimum Exposure Time</th><th>Minimum Dry Time</th></tr>
<tr><td>Gravity Displacement</td><td>250°F (121°C)</td><td>30 Minutes</td><td>15 Minutes</td></tr>
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<tr><td>Pre-Vacuum</td><td>270°F (132°C)</td><td>4 Minutes</td><td>30 Minutes</td></tr>
<tr><td>Pre-Vacuum</td><td>275°F (135°C)</td><td>3 Minutes</td><td>16 Minutes</td></tr>
</table>
*Refer to Indications for Use for immediate use sterilization parameters (unwrapped).</td><td>
<table>
<tr><th>Steam Sterilization Cycle</th><th>Minimum Exposure Temperature</th><th>Minimum Exposure Time</th><th>Minimum Dry Time</th></tr>
<tr><td>Gravity Displacement</td><td>250°F (121°C)</td><td>55 Minutes</td><td>20-50 Minutes as needed</td></tr>
<tr><td>Gravity Displacement</td><td>270°F (132°C)</td><td>30 Minutes</td><td>20-50 Minutes as needed</td></tr>
<tr><td>Pre-Vacuum</td><td>270°F (132°C)</td><td>4 Minutes</td><td>20-40 Minutes as needed</td></tr>
</table>
</td><td>Similar</td></tr>
<tr><td>Reusable</td><td>Yes, validated to be reused at least five (5) times.</td><td>Yes</td><td>Similar</td></tr>
<tr><td>Material Compatibility with Sterilization Method</td><td>Yes - Materials are compatible with sterilization method</td><td>Yes - Materials are compatible with sterilization method</td><td>Same</td></tr>
<tr><td>Sterilant Penetration Studies</td><td>Yes – Sterilant (steam) penetration through perforations in base and lid - Steam Sterilization Validation testing</td><td>Yes – Sterilant (steam) penetration through perforations in base and lid - Steam Sterilization Validation testing</td><td>Same</td></tr>
</table>

Element	**Subject Device** *Steri-Cassette and Steri-Cage*	**Predicate Device (K012105)** PolyVac Surgical Instrument Delivery System's *Instrument Cassettes*	**Subject Device** **vs.** **Predicate Device**
Microbial Barrier Studies (packaging integrity to maintain sterility)	To be used with a validated, FDA-cleared sterilization wrap	To be used with a validated, FDA-cleared sterilization wrap	Same
Material Compatibility with Repeat Sterilization	Yes - Materials are compatible with repeated sterilization cycles per validation testing. Materials of construction are compatible with steam sterilization.	Yes - Materials are compatible with repeated sterilization cycles.	Similar
– SAFETY / BIOCOMPATIBILITY ASSESSMENT –			
Toxicological Properties	Yes - Materials are known to be biocompatible and do not come into direct contact with patient.	Yes - Materials are known to be biocompatible and do not come into direct contact with patient.	Same
Patient Contact	No	No	Same
Blood/Fluid Contact	None	None	Same
– PACKAGING INTEGRITY –			
Packaging	Non-Sterile Plastic Wrap	Non-Sterile - Specific packaging not stated in predicate's 510(k) summary.	Same
Labeling	Labeled Plastic Wrap Containing Device and Cleaning and Sterilization IFU	Labeled Polybag Containing Device and Cleaning and Sterilization IFU	Similar
Distribution Process	Shipped Non-Sterile	Shipped Non-Sterile	Same

F. Non-clinical Performance Testing

Testing was conducting in accordance with the following standards:

- ISO 10993-1:2009 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process)
- ISO 7405:2008 (Dentistry - Evaluation of biocompatibility of medical devices used in dentistry)
- ISO 17664:2004 (Sterilization of medical devices – Information to be provided by the manufacturer for the processing of sterilizable medical devices)
- ANSI/AAMI/ISO 17665-1:2006 (Sterilization of health care products – Moist Heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices)
- ISO14937:2000 (Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices)
- AAMI TIR12:2010 (Designing, testing, and labeling for reprocessing in health care facilities: A guide for medical device manufacturers)
- AAMI TIR30:2011 (A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices)
- AAMI ST77, Rev. 2013 (Containment devices for reusable medical device sterilization)
- ANSI/AAMI ST79:2010 (Comprehensive guide to steam sterilization and sterility assurance in health care facilities)

H. Conclusion

Based on the intended use, indications for use, technological characteristics, performance data and comparison to the predicate device, the subject Steri-Cassette and Steri-Cage product line has been shown to be substantially equivalent to the legally marketed predicate device PolyVac Surgical Instrument Delivery System's Instrument Cassettes (K012105).