



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

April 14, 2016

Symmetry Surgical, Inc.  
c/o Ms. Michele Lucey  
Regulatory Affairs Consultant  
Lakeshore Medical Device Consulting LLC  
128 Blye Hill Landing  
Newbury, NH 03255

Re: K152111

Trade/Device Name: Symmetry Surgical Quad-Lock™ Container System  
Regulation Number: 21 CFR 880.6850  
Regulation Name: Sterilization wrap  
Regulatory Class: Class II  
Product Code: KCT  
Dated: March 11, 2016  
Received: March 15, 2016

Dear Ms. Michele Lucey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

*Tejashri Purohit-Sheth, M.D.*

**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

## Indications for Use

510(k) Number (if known)  
K152111

Device Name  
Symmetry Surgical Quad-Lock® Container System

Indications for Use (Describe)  
Indications for Use:

The Symmetry Surgical Quad-Lock® Container System is indicated for use by hospitals and by health care facilities to:

- organize and protect stainless steel, aluminum, titanium, plastic\* and silicone surgical instruments that will be sterilized
- allow sterilization of the contained instruments by prevacuum steam, ethylene oxide, and low temperature hydrogen peroxide sterilization cycles (validated modalities and parameters are shown in Table 1)
- When sterilized by prevacuum steam sterilization, the Quad-Lock® Containers maintain the sterility of the contents for up to 180 days during storage and transport within the healthcare facility, as long as the integrity of the container has not been compromised
- When sterilized by ethylene oxide or low temperature hydrogen peroxide cycle types the Quad-Lock® Containers maintain the sterility of the contents when sterilized by any of the above for up to 30 days during storage and transport within the healthcare facility, as long as the integrity of the container has not been compromised

The system has not been tested for maintenance of sterility after transportation outside the health care facility. The system is intended for use with stainless steel, aluminum, titanium, plastic and silicone surgical instruments.

\*The use of plastic instruments has only been confirmed for steam sterilization.

For effective sterilization and drying of any size Symmetry Surgical Quad-Lock® Sterilization Container, the recommended maximum combined weight of the single container, lid, basket/tray and basket/tray contents is defined in Table 1. For each cycle type the qualified lumen size is the minimum diameter and maximum length that has been qualified for use are shown in Table 1. Container System Compatibility by Cycle Type details are shown in Table 2.

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.

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Table 1 Sterilization Parameters					
Sterilization Modality	Cycle Type	Cycle Parameters	Instrument Type	Qualified Lumen Size/Maximum Quantity	Load Requirements (Maximum Weight)
Steam	Prevacuum	Temperature: 132°C Exposure Time: 4 minutes Drying Time: 30 minutes  Stackable – Yes, up to three containers	stainless steel, aluminum, titanium, plastic* and silicone surgical instruments	<b>Full and Three Quarter Sizes :</b> 3 mm x 400mm  <b>Half Size:</b> 3mm x 250mm size  4 lumen per container	<b>Full, Three Quarter and Half Sizes:</b>  25 lbs
Ethylene Oxide	100% ETO	Concentration: 725mg/L Temperature: 55°C Exposure Time: 60 minutes Humidity: 50-70% Aeration time 8 hours at 110°F (43°C) Stackable – No	stainless steel, aluminum, titanium, and silicone surgical instruments	<b>Full and Three Quarter Sizes:</b> 3 mm x 400mm  <b>Half Size:</b> 2mm x 250mm  4 Lumen per container	<b>Full, Three Quarter and Half Sizes:</b>  25 lbs
<b>Low Temperature H<sub>2</sub>O<sub>2</sub> Sterilizers by Model Name/Cycle Type</b> Sterilization Parameters for each cycle type are set by the manufacturer					
STERRAD 100NX	Standard	Fixed Cycle Type** Stackable – No	stainless steel, aluminum, titanium, and, silicone surgical instruments	<b>Full Size:</b> 2mm x 400mm  <b>Three Quarter and Half Sizes:</b> 2mm x 250mm  5 Lumen per container	<b>Full Size:</b> 21.4 lb  <b>Three Quarter and Half Sizes:</b> 13.85 lbs

Table 1 Sterilization Parameters					
Sterilization Modality	Cycle Type	Cycle Parameters	Instrument Type	Qualified Lumen Size/Maximum Quantity	Load Requirements (Maximum Weight)
	DUO	Fixed Cycle Type** Stackable – No	stainless steel, aluminum, titanium, and, silicone surgical instruments	<b>Full Size:</b> 2mm x 400mm  <b>Three Quarter and Half Sizes:</b> 2mm x 250mm  5 Lumen per container	<b>Full Size:</b> 21.4 lbs  <b>Three Quarter and Half Sizes:</b> 13.2 lbs
	FLEX	Fixed Cycle Type** Stackable - No	Porous Lumens	<b>Full, Three Quarter and Half Sizes:</b> One 1mm x 850mm Flexible Endoscope per container	<b>Full Size:</b> 16.65 lbs  <b>Three Quarter Size:</b> 12.40 lbs  <b>Half Size:</b> 10.75 lbs
STERRAD NX	Standard	Fixed Cycle Type** Stackable - No	stainless steel, aluminum, titanium, and, silicone surgical instruments	<b>Full Size:</b> 1mm x 400mm  <b>Three Quarter and Half Size:</b> 2mm x 250mm  5 Lumen per container	<b>Full Size:</b> 21.4 lbs  <b>Three Quarter and Half Sizes:</b> 13.85 lbs
	Advanced	Fixed Cycle Type** Stackable - No	stainless steel, aluminum, titanium, and, silicone surgical instruments	<b>Full, Three Quarter, and Half Sizes:</b> 2mm x 250mm  5 Lumen per container	<b>Full Size:</b> 21.4 lbs  <b>Three Quarter and Half Sizes:</b> 13.85 lbs

Table 1 Sterilization Parameters					
Sterilization Modality	Cycle Type	Cycle Parameters	Instrument Type	Qualified Lumen Size/Maximum Quantity	Load Requirements (Maximum Weight)
STERRAD 100S	Standard	Fixed Cycle Type** Stackable - No	stainless steel, aluminum, titanium, and, silicone surgical instruments	<b>Full Size:</b> 3mm x 400mm  <b>Three Quarter and Half Size:</b> 2mm x 250mm  5 Lumen per container	<b>Full, Three Quarter, and Half Sizes:</b> 18.2 lbs
STERIS V-PRO™ 1 PLUS	Lumen or No Lumen	Cycle time = 55 minutes Stackable - No	stainless steel, aluminum, titanium, and, silicone surgical instruments	<b>Full Size:</b> 3mm x 400mm  <b>Three Quarter and Half Sizes:</b> 2mm x 250mm  10 lumen per container	<b>Full, Three Quarter, and Half Sizes:</b> 19.65 lbs

\*The use of plastic instruments has only been confirmed for steam sterilization.

\*\*For all STERRAD manufactured sterilizers all cycle parameters are preset by the manufacturer and cannot be reset by the user.

Table 2 Container System Compatibility by Cycle Type					
Product Code	Size	Pre-Vacuum Steam	100% Ethylene Oxide	STERRAD 100S NX Standard NX Advanced 100NX Standard 100NX FLEX 100NX DUO	STERIS V-Pro 1 Plus Lumen
Container Component Compatibility					
Filter Bottom Container Base					
Full Length	Height				
508726	100mm (4 inch)	YES	YES	YES	YES
508727	135mm (5 inch)	YES	YES	YES	YES
508728	150mm (6 inch)	YES	YES	YES	YES
508729	200mm (8 inch)	YES	YES	YES	YES
508730	260mm (10 inch)	YES	YES	YES	YES
Three-Quarter Length					
508736	100mm (4 inch)	YES	YES	YES	YES
508737	135mm (5 inch)	YES	YES	YES	YES
508738	150mm (6 inch)	YES	YES	YES	YES
Half Length					
508731	100mm (4 inch)	YES	YES	YES	YES
508732	135mm (5 inch)	YES	YES	YES	YES
508733	150mm (6 inch)	YES	YES	YES	YES
508734	200mm (8 inch)	YES	YES	YES	YES
508735	260mm (10 inch)	YES	YES	YES	YES
Solid Bottom Container Base					
Full Length					
508739	100mm (4 inch)	YES	YES	NO	NO
508740	135mm (5 inch)	YES	YES	NO	NO
508741	150mm (6 inch)	YES	YES	NO	NO

Table 2 Container System Compatibility by Cycle Type					
Product Code	Size	Pre-Vacuum Steam	100% Ethylene Oxide	STERRAD 100S NX Standard NX Advanced 100NX Standard 100NX FLEX 100NX DUO	STERIS V-Pro 1 Plus Lumen
Container Component Compatibility					
508742	200mm (8 inch)	YES	YES	NO	NO
508743	260mm (10 inch)	YES	YES	NO	NO
Three-Quarter Length					
508749	100mm (4 inch)	YES	YES	NO	NO
508750	135mm (5 inch)	YES	YES	NO	NO
508751	150mm (6 inch)	YES	YES	NO	NO
Half Length					
508744	100mm (4 inch)	YES	YES	NO	NO
508745	135mm (5 inch)	YES	YES	NO	NO
508746	150mm (6 inch)	YES	YES	NO	NO
508747	200 (8 inch)	YES	YES	NO	NO
508748	260 (10 inch)	YES	YES	NO	NO
Filter Lids					
Product Code	Color				
Full Length					
508944	Grey	YES	YES	YES	YES
508945	Yellow	YES	NO	NO	NO
508946	Green	YES	NO	NO	NO
508947	Blue	YES	NO	NO	NO
508948	Red	YES	NO	NO	NO
508949	Black	YES	NO	NO	NO
Three-Quarter Length					
508956	Grey	YES	YES	YES	YES
508957	Yellow	YES	NO	NO	NO

Table 2 Container System Compatibility by Cycle Type					
Product Code	Size	Pre-Vacuum Steam	100% Ethylene Oxide	STERRAD 100S NX Standard NX Advanced 100NX Standard 100NX FLEX 100NX DUO	STERIS V-Pro 1 Plus Lumen
Container Component Compatibility					
508958	Green	YES	NO	NO	NO
508959	Blue	YES	NO	NO	NO
508960	Red	YES	NO	NO	NO
508961	Black	YES	NO	NO	NO
Half Length					
508950	Grey	YES	YES	YES	YES
508951	Yellow	YES	NO	NO	NO
508952	Green	YES	NO	NO	NO
508953	Blue	YES	NO	NO	NO
508954	Red	YES	NO	NO	NO
508955	Black	YES	NO	NO	NO
Security Lids					
Product Code	Color				
Full Length					
508869	Grey	YES	YES	YES	YES
508870	Yellow	YES	YES	YES	YES
508871	Green	YES	YES	YES	YES
508872	Blue	YES	YES	YES	YES
508873	Red	YES	YES	YES	YES
508874	Black	YES	YES	YES	YES
Three-Quarter Length					
508881	Grey	YES	YES	YES	YES
508882	Yellow	YES	YES	YES	YES
508883	Green	YES	YES	YES	YES
508884	Blue	YES	YES	YES	YES

Table 2 Container System Compatibility by Cycle Type					
Product Code	Size	Pre-Vacuum Steam	100% Ethylene Oxide	STERRAD 100S NX Standard NX Advanced 100NX Standard 100NX FLEX 100NX DUO	STERIS V-Pro 1 Plus Lumen
Container Component Compatibility					
508885	Red	YES	YES	YES	YES
508886	Black	YES	YES	YES	YES
Half Length					
508875	Grey	YES	YES	YES	YES
508876	Yellow	YES	YES	YES	YES
508877	Green	YES	YES	YES	YES
508878	Blue	YES	YES	YES	YES
508879	Red	YES	YES	YES	YES
508880	Black	YES	YES	YES	YES
Basket Configurations					
Product Code	Height				
Full Length					
508500	30mm (1 inch)	YES	YES	YES	YES
508501	50mm (2 inch)	YES	YES	YES	YES
508502	70mm (3 inch)	YES	YES	YES	YES
508503	100mm (4 inch)	YES	YES	YES	YES
Three-Quarter Length					
508508	30mm (1 inch)	YES	YES	YES	YES
508509	50mm (2 inch)	YES	YES	YES	YES
508510	70mm (3 inch)	YES	YES	YES	YES
508511	100mm (4 inch)	YES	YES	YES	YES
Half Length					
508504	30mm (1 inch)	YES	YES	YES	YES
508505	50mm (2 inch)	YES	YES	YES	YES

Table 2 Container System Compatibility by Cycle Type						
Product Code	Size	Pre-Vacuum Steam	100% Ethylene Oxide	STERRAD 100S NX Standard NX Advanced 100NX Standard 100NX FLEX 100NX DUO	STERIS V-Pro 1 Plus Lumen	
Container Component Compatibility						
508506	70mm (3 inch)	YES	YES	YES	YES	YES
508507	100mm (4 inch)	YES	YES	YES	YES	YES
Wire Base Configurations						
Product Code	Length	Height				
508512	Half	26mm (1 inch)	YES	YES	YES	YES
508513	Three-Quarter	26mm (1 inch)	YES	YES	YES	YES
508514	Full	26mm (1 inch)	YES	YES	YES	YES
Protective Mat						
Product Code	Length					
508550	Half	YES	YES	NO	YES	YES
508551	Three-Quarter	YES	YES	NO	YES	YES
508552	Full	YES	YES	NO	YES	YES

## K152111

### 510(k) Summary As required by 21 CFR 807.92

Date Prepared: April 8, 2016

Company Name: Symmetry Surgical, Inc.  
3034 Owen Drive, Antioch TN 37013  
1-800-251-3000  
1-615-964-5567 (fax)

Contact Person Michele Lucey  
Lakeshore Medical Device Consulting LLC  
128 Blye Hill Landing  
Newbury NH  
603-763-3455  
Lucey\_m@msn.com

Device Proprietary Name: Symmetry Surgical Quad-Lock<sup>®</sup> Container System  
Container System Device Common Name: Container Sterilization System

Classification Name: Container Sterilization System

Device Classification: Class II (21 CFR 880.6850) (KCT)

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Type of 510(k) Submission: Traditional 510(k)

Basis for Submission: Expand Indications for Use

Predicate Device(s): K092437, K120117 Codman<sup>™</sup> Sterilization Container

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#### **Device Description:**

The Symmetry Surgical Quad-Lock<sup>®</sup> Container System provides a means to organize and protect stainless steel, aluminum, titanium, plastic and silicone surgical instruments during sterilization and storage. The filter lids, security lids, and container bottoms are made from anodized aluminum. The security lids help ensure sterility during storage and protect the container lid when the containers are stacked. The Container System includes the container base, filter lid, security lid, filters and other accessories.

#### **Indications for Use:**

Intended Use:

The Symmetry Surgical Quad-Lock<sup>®</sup> Container System is indicated for use by hospitals and by health care facilities to:

- organize and protect stainless steel, aluminum, titanium, plastic\* and silicone surgical instruments that will be sterilized

- allow sterilization of the contained instruments by prevacuum steam, ethylene oxide, and low temperature hydrogen peroxide sterilization cycles (validated modalities and parameters are shown in Table 1)
- When sterilized by prevacuum steam sterilization, the Quad-Lock® Containers maintain the sterility of the contents for up to 180 days during storage and transport within the healthcare facility, as long as the integrity of the container has not been compromised
- When sterilized by ethylene oxide or low temperature hydrogen peroxide cycle types the Quad-Lock® Containers maintain the sterility of the contents when sterilized by any of the above for up to 30 days during storage and transport within the healthcare facility, as long as the integrity of the container has not been compromised

The system has not been tested for maintenance of sterility after transportation outside the health care facility.

The system is intended for use with stainless steel, aluminum, titanium, plastic\* and silicone surgical instruments.

\*The use of plastic instruments has only been confirmed for steam sterilization.

For effective sterilization and drying of any size Symmetry Surgical Quad-Lock® Sterilization Container, the recommended maximum combined weight of the single container, lid, basket/tray and basket/tray contents is defined in Table 1. For each cycle type the qualified lumen size is the minimum diameter and maximum length that has been qualified for use are shown in Table 1. Container System Compatibility by Cycle Type details are shown in Table 2.

<b>Table 1 Sterilization Parameters</b>					
<b>Sterilization Modality</b>	<b>Cycle Type</b>	<b>Cycle Parameters*</b>	<b>Instrument Type</b>	<b>Qualified Lumen Size/Maximum Quantity</b>	<b>Load Requirements (Maximum Weight)</b>
Steam	Prevacuum	Temperature: 132°C Exposure Time: 4 minutes Drying Time: 30 minutes  Stackable – Yes, up to three containers	stainless steel, aluminum, titanium, plastic* and silicone surgical instruments	<b>Full and Three Quarter Sizes :</b> 3 mm x 400mm  <b>Half Size:</b> 3mm x 250mm size  4 lumen per container	<b>Full, Three Quarter and Half Sizes:</b>  25 lbs
Ethylene Oxide	100% ETO	Concentration: 725mg/L Temperature: 55°C Exposure Time: 60 minutes Humidity: 50-70% Aeration time 8	stainless steel, aluminum, titanium, and silicone surgical instruments	<b>Full and Three Quarter Sizes:</b> 3 mm x 400mm  <b>Half Size:</b> 2mm x 250mm  4 Lumen per container	<b>Full, Three Quarter and Half Sizes:</b>  25 lbs

Table 1 Sterilization Parameters					
Sterilization Modality	Cycle Type	Cycle Parameters*	Instrument Type	Qualified Lumen Size/Maximum Quantity	Load Requirements (Maximum Weight)
		hours at 110°F (43°C) Stackable – No			
Low Temperature H <sub>2</sub> O <sub>2</sub> Sterilizers by Model Name/Cycle Type Sterilization Parameters for each cycle type are set by the manufacturer					
STERRAD 100NX	Standard	Fixed Cycle Type** Stackable – No	stainless steel, aluminum, titanium, and, silicone surgical instruments	<b>Full Size:</b> 2mm x 400mm  <b>Three Quarter and Half Sizes:</b> 2mm x 250mm  5 Lumen per container	<b>Full Size:</b> 21.4 lb  <b>Three Quarter and Half Sizes:</b> 13.85 lbs
	DUO	Fixed Cycle Type** Stackable – No	stainless steel, aluminum, titanium, and, silicone surgical instruments	<b>Full Size:</b> 2mm x 400mm  <b>Three Quarter and Half Sizes:</b> 2mm x 250mm  5 Lumen per container	<b>Full Size:</b> 21.4 lbs  <b>Three Quarter and Half Sizes:</b> 13.2 lbs
	FLEX	Fixed Cycle Type** Stackable - No	Porous Lumens	<b>Full, Three Quarter and Half Sizes:</b> One 1mm x 850mm Flexible Endoscope per container	<b>Full Size:</b> 16.65 lbs  <b>Three Quarter Size :</b> 12.40 lbs  <b>Half Size:</b> 10.75 lbs
STERRAD NX	Standard	Fixed Cycle Type** Stackable - No	stainless steel, aluminum, titanium, and, silicone surgical instruments	<b>Full Size:</b> 1mm x 400mm  <b>Three Quarter and Half Size:</b> 2mm x 250mm	<b>Full Size:</b> 21.4 lbs  <b>Three Quarter and Half Sizes:</b> 13.85 lbs

Table 1 Sterilization Parameters					
Sterilization Modality	Cycle Type	Cycle Parameters*	Instrument Type	Qualified Lumen Size/Maximum Quantity	Load Requirements (Maximum Weight)
				5 Lumen per container	
	Advanced	Fixed Cycle Type** Stackable - No	stainless steel, aluminum, titanium, and, silicone surgical instruments	<b>Full, Three Quarter, and Half Sizes:</b> 2mm x 250mm 5 Lumen per container	<b>Full Size:</b> 21.4 lbs <b>Three Quarter and Half Sizes:</b> 13.85 lbs
STERRAD 100S	Standard	Fixed Cycle Type** Stackable - No	stainless steel, aluminum, titanium, and, silicone surgical instruments	<b>Full Size:</b> 3mm x 400mm <b>Three Quarter and Half Size:</b> 2mm x 250mm 5 Lumen per container	<b>Full, Three Quarter, and Half Sizes:</b> 18.2 lbs
STERIS V-PRO™ 1 PLUS	Lumen or No Lumen	Cycle time = 55 minutes Stackable - No	stainless steel, aluminum, titanium, and, silicone surgical instruments	<b>Full Size:</b> 3mm x 400mm <b>Three Quarter and Half Sizes:</b> 2mm x 250mm 10 lumen per container	<b>Full, Three Quarter, and Half Sizes:</b> 19.65 lbs

\*The use of plastic instruments has only been confirmed for steam sterilization

\*\*For all STERRAD manufactured sterilizers all cycle parameters are preset by the manufacturer and cannot be reset by the user.

<b>Table 2</b>					
<b>Container System Compatibility by Cycle Type</b>					
<b>Product Code</b>	<b>Size</b>	<b>Pre-Vacuum Steam</b>	<b>100% Ethylene Oxide</b>	<b>STERRAD 100S NX Standard NX Advanced 100NX Standard 100NX FLEX 100NX DUO</b>	<b>STERIS V-Pro 1 Plus Lumen</b>
<b>Container Component Compatibility</b>					
<b>Filter Bottom Container Base</b>					
<b>Full Length</b>	<b>Height</b>				
508726	100mm (4 inch)	YES	YES	YES	YES
508727	135mm (5 inch)	YES	YES	YES	YES
508728	150mm (6 inch)	YES	YES	YES	YES
508729	200mm (8 inch)	YES	YES	YES	YES
508730	260mm (10 inch)	YES	YES	YES	YES
<b>Three-Quarter Length</b>					
508736	100mm (4 inch)	YES	YES	YES	YES
508737	135mm (5 inch)	YES	YES	YES	YES
508738	150mm (6 inch)	YES	YES	YES	YES
<b>Half Length</b>					
508731	100mm (4 inch)	YES	YES	YES	YES
508732	135mm (5 inch)	YES	YES	YES	YES
508733	150mm (6 inch)	YES	YES	YES	YES
508734	200mm (8 inch)	YES	YES	YES	YES
508735	260mm (10 inch)	YES	YES	YES	YES
<b>Solid Bottom Container Base</b>					
<b>Full Length</b>					
508739	100mm (4 inch)	YES	YES	NO	NO
508740	135mm (5 inch)	YES	YES	NO	NO
508741	150mm (6 inch)	YES	YES	NO	NO
508742	200mm (8 inch)	YES	YES	NO	NO
508743	260mm (10 inch)	YES	YES	NO	NO
<b>Three-Quarter Length</b>					
508749	100mm (4 inch)	YES	YES	NO	NO
508750	135mm (5 inch)	YES	YES	NO	NO
508751	150mm (6 inch)	YES	YES	NO	NO
<b>Half Length</b>					
508744	100mm (4 inch)	YES	YES	NO	NO
508745	135mm (5 inch)	YES	YES	NO	NO
508746	150mm (6 inch)	YES	YES	NO	NO
508747	200 (8 inch)	YES	YES	NO	NO
508748	260 (10 inch)	YES	YES	NO	NO

<b>Table 2</b>					
<b>Container System Compatibility by Cycle Type</b>					
<b>Product Code</b>	<b>Size</b>	<b>Pre-Vacuum Steam</b>	<b>100% Ethylene Oxide</b>	<b>STERRAD 100S NX Standard NX Advanced 100NX Standard 100NX FLEX 100NX DUO</b>	<b>STERIS V-Pro 1 Plus Lumen</b>
<b>Container Component Compatibility</b>					
<b>Filter Lids</b>					
<b>Product Code</b>	<b>Color</b>				
<b>Full Length</b>					
508944	Grey	YES	YES	YES	YES
508945	Yellow	YES	NO	NO	NO
508946	Green	YES	NO	NO	NO
508947	Blue	YES	NO	NO	NO
508948	Red	YES	NO	NO	NO
508949	Black	YES	NO	NO	NO
<b>Three-Quarter Length</b>					
508956	Grey	YES	YES	YES	YES
508957	Yellow	YES	NO	NO	NO
508958	Green	YES	NO	NO	NO
508959	Blue	YES	NO	NO	NO
508960	Red	YES	NO	NO	NO
508961	Black	YES	NO	NO	NO
<b>Half Length</b>					
508950	Grey	YES	YES	YES	YES
508951	Yellow	YES	NO	NO	NO
508952	Green	YES	NO	NO	NO
508953	Blue	YES	NO	NO	NO
508954	Red	YES	NO	NO	NO
508955	Black	YES	NO	NO	NO
<b>Security Lids</b>					
<b>Product Code</b>	<b>Color</b>				
<b>Full Length</b>					
508869	Grey	YES	YES	YES	YES
508870	Yellow	YES	YES	YES	YES
508871	Green	YES	YES	YES	YES
508872	Blue	YES	YES	YES	YES
508873	Red	YES	YES	YES	YES
508874	Black	YES	YES	YES	YES
<b>Three-Quarter Length</b>					
508881	Grey	YES	YES	YES	YES
508882	Yellow	YES	YES	YES	YES
508883	Green	YES	YES	YES	YES
508884	Blue	YES	YES	YES	YES

<b>Table 2</b>						
<b>Container System Compatibility by Cycle Type</b>						
<b>Product Code</b>	<b>Size</b>	<b>Pre-Vacuum Steam</b>	<b>100% Ethylene Oxide</b>	<b>STERRAD 100S NX Standard NX Advanced 100NX Standard 100NX FLEX 100NX DUO</b>	<b>STERIS V-Pro 1 Plus Lumen</b>	
<b>Container Component Compatibility</b>						
508885	Red	YES	YES	YES	YES	
508886	Black	YES	YES	YES	YES	
<b>Half Length</b>						
508875	Grey	YES	YES	YES	YES	
508876	Yellow	YES	YES	YES	YES	
508877	Green	YES	YES	YES	YES	
508878	Blue	YES	YES	YES	YES	
508879	Red	YES	YES	YES	YES	
508880	Black	YES	YES	YES	YES	
<b>Basket Configurations</b>						
<b>Product Code</b>	<b>Height</b>					
<b>Full Length</b>						
508500	30mm (1 inch)	YES	YES	YES	YES	
508501	50mm (2 inch)	YES	YES	YES	YES	
508502	70mm (3 inch)	YES	YES	YES	YES	
508503	100mm (4 inch)	YES	YES	YES	YES	
<b>Three-Quarter Length</b>						
508508	30mm (1 inch)	YES	YES	YES	YES	
508509	50mm (2 inch)	YES	YES	YES	YES	
508510	70mm (3 inch)	YES	YES	YES	YES	
508511	100mm (4 inch)	YES	YES	YES	YES	
<b>Half Length</b>						
508504	30mm (1 inch)	YES	YES	YES	YES	
508505	50mm (2 inch)	YES	YES	YES	YES	
508506	70mm (3 inch)	YES	YES	YES	YES	
508507	100mm (4 inch)	YES	YES	YES	YES	
<b>Wire Base Configurations</b>						
<b>Product Code</b>	<b>Length</b>	<b>Height</b>				
508512	Half	26mm (1 inch)	YES	YES	YES	YES
508513	Three-Quarter	26mm (1 inch)	YES	YES	YES	YES
508514	Full	26mm (1 inch)	YES	YES	YES	YES

<b>Table 2</b>					
<b>Container System Compatibility by Cycle Type</b>					
<b>Product Code</b>	<b>Size</b>	<b>Pre-Vacuum Steam</b>	<b>100% Ethylene Oxide</b>	<b>STERRAD 100S NX Standard NX Advanced 100NX Standard 100NX FLEX 100NX DUO</b>	<b>STERIS V-Pro 1 Plus Lumen</b>
<b>Container Component Compatibility</b>					
<b>Protective Mat</b>					
<b>Product Code</b>	<b>Length</b>				
508550	Half	YES	YES	NO	YES
508551	Three-Quarter	YES	YES	NO	YES
508552	Full	YES	YES	NO	YES

**Technological Characteristics:**

The technological characteristics of this device, including design and materials, are similar to the predicate device, Codman™ Sterilization Container (K092437, K120117). Table 3 provides a summary of the device characteristics compared to the predicate device:

<b>Table 3 Substantial Equivalence Comparison</b>			
<b>Similarities and Differences</b>	<b>Predicate Symmetry Surgical Quad-Lock® Container Systems (Previously Codman)</b>	<b>Predicate Symmetry Surgical Quad-Lock® Container Systems (Previously Codman)</b>	<b>Proposed Symmetry Surgical Quad-Lock® Container Systems</b>
510(k) Number	K092437	K120117	This Submission
Trade Name	Codman Sterilization Containers	Codman® Sterilization Containers	Symmetry Surgical Quad-Lock® Container Systems
510(k) Decision Date	March 25, 2010	April 16, 2012	NA
FDA Product Code	KCT	Same	Same
Classification Section	21CFR880.6850	Same	Same
Classification Name	Sterilization wrap containers, trays, cassettes & other accessories	Same	Same
Use Description	Means to organize and protect instruments during sterilization and storage	Same	Same
Materials	Aluminum alloy, Stainless Steel & Silicone	Same	Same
Indications for Use	<p>The Symmetry Surgical Quad-Lock® Sterilization Container System is indicated for use by hospitals and by health care facilities to:</p> <ul style="list-style-type: none"> <li>organize and protect stainless steel, aluminum, and titanium general surgical instruments that will be sterilized</li> <li>allow sterilization of the contained instruments by prevacuum steam sterilization</li> </ul> <p>maintain the sterility of the contents for up to 180 days during storage and transport within the health care facility, as long as the integrity of the container has not been compromised</p>	<p>The Symmetry Surgical Quad-Lock® Sterilization Container System is indicated for use by hospitals and by health care facilities to:</p> <ul style="list-style-type: none"> <li>organize and protect stainless steel, aluminum, titanium, plastic and silicone surgical instruments that will be sterilized</li> <li>allow sterilization of the contained instruments by prevacuum steam sterilization</li> </ul> <p>maintain the sterility of the contents for up to 180 days during storage and transport within the health care facility, as long as the integrity of the container has not been</p>	<p>The Symmetry Surgical Quad-Lock® is indicated for use by hospitals and by health care facilities to:</p> <ul style="list-style-type: none"> <li>organize and protect stainless steel, aluminum, titanium, plastic* and silicone surgical instruments that will be sterilized</li> <li>allow sterilization of the contained instruments by prevacuum steam, ethylene oxide, and low temperature hydrogen peroxide sterilization cycles (validated parameters shown in Table 1)</li> <li>When sterilized by prevacuum steam sterilization, the Quad-Lock® Containers maintain the sterility of the contents for up to 180 days during storage and transport within the healthcare facility, as long as the integrity of the container has not been compromised</li> <li>When sterilized by ethylene oxide or low temperature hydrogen peroxide cycle types the Quad-Lock® Containers maintain the sterility of the contents when sterilized by any of the above for up to 30 days during storage and transport within the healthcare facility, as long as the integrity of the container has not been compromised</li> </ul> <p>New modalities have been validated to demonstrate efficacy. No new issues are raised due to these</p>

**Table 3  
Substantial Equivalence Comparison**

<b>Similarities and Differences</b>	<b>Predicate Symmetry Surgical Quad-Lock® Container Systems (Previously Codman)</b>	<b>Predicate Symmetry Surgical Quad-Lock® Container Systems (Previously Codman)</b>	<b>Proposed Symmetry Surgical Quad-Lock® Container Systems</b>		
		compromised	differences. *The inclusion of plastic instruments applies only to steam sterilization.		
Materials	Aluminum, stainless steel, polycarbonate, silicone, nylon	Same	Same		
Stacking	Caution: Do not stack the containers in the sterilizer	The Symmetry Surgical Quad-Lock® Container Systems can be stacked during sterilization with up to three containers.	Same as K120117		
Volume to Vent Ratio mm <sup>3</sup> /mm <sup>2</sup>	1004-5316	Same	Same		
Energy modality	None	Same	Same		
Maximum Weight of Container	For effective sterilization and drying of any size Symmetry Surgical Quad-Lock® Container Systems, the recommended maximum combined weight of the single container, lid, basket and basket contents is 25 lb. (11.3 kg).	Same	For effective sterilization and drying of any size Symmetry Surgical Quad-Lock® Container Systems, the recommended maximum combined weight of the single container, lid, basket and basket contents is defined for each container type. The weights are similar to the predicate.  Container weights are specified in the labeling. No new issues are raised due to these differences.		
Sterilization Parameters	Cycle Type – Pre-vacuum Temperature - 132°C Exposure Time – 4 minutes Drying Time – 30 minutes	Same	<b>Sterilization Parameters</b>		
			<b>Sterilization Modality</b>	<b>Cycle Type</b>	<b>Cycle Parameters</b>
			Steam	Prevacuum	Temperature: 132°C Exposure Time: 4 minutes Drying Time: 30 minutes Stackable – Yes, up to three containers
Ethylene Oxide	100% ETO	Concentration: 725mg/L Temperature: 55°C Exposure Time: 60 minutes Humidity: 50-70% Stackable – No			

**Table 3  
Substantial Equivalence Comparison**

Similarities and Differences	Predicate Symmetry Surgical Quad-Lock® Container Systems (Previously Codman)	Predicate Symmetry Surgical Quad-Lock® Container Systems (Previously Codman)	Proposed Symmetry Surgical Quad-Lock® Container Systems																				
			<table border="1" data-bbox="982 569 1458 995"> <tr> <td colspan="2">Low Temperature H<sub>2</sub>O<sub>2</sub> Sterilizers by Model Name/Cycle Type</td> </tr> <tr> <td colspan="2">Sterilization Parameters for each cycle type are set by the manufacturer</td> </tr> <tr> <td colspan="2">Stackable – No</td> </tr> <tr> <td colspan="2">Silicone Mat – Not compatible with Low Temperature H<sub>2</sub>O<sub>2</sub> sterilization cycles</td> </tr> <tr> <td rowspan="3">STERRAD 100NX</td> <td>Standard</td> </tr> <tr> <td>DUO</td> </tr> <tr> <td>FLEX</td> </tr> <tr> <td rowspan="2">STERRAD NX</td> <td>Standard</td> </tr> <tr> <td>Advanced</td> </tr> <tr> <td>STERRAD 100S</td> <td>Standard</td> </tr> <tr> <td rowspan="2">V-PRO™ 1 PLUS</td> <td>Lumen</td> </tr> <tr> <td>No Lumen</td> </tr> </table> <p>New modalities have been validated to demonstrate efficacy. No new issues are raised due to these differences.</p>	Low Temperature H <sub>2</sub> O <sub>2</sub> Sterilizers by Model Name/Cycle Type		Sterilization Parameters for each cycle type are set by the manufacturer		Stackable – No		Silicone Mat – Not compatible with Low Temperature H <sub>2</sub> O <sub>2</sub> sterilization cycles		STERRAD 100NX	Standard	DUO	FLEX	STERRAD NX	Standard	Advanced	STERRAD 100S	Standard	V-PRO™ 1 PLUS	Lumen	No Lumen
Low Temperature H <sub>2</sub> O <sub>2</sub> Sterilizers by Model Name/Cycle Type																							
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	DUO																						
	FLEX																						
STERRAD NX	Standard																						
	Advanced																						
STERRAD 100S	Standard																						
V-PRO™ 1 PLUS	Lumen																						
	No Lumen																						
Storage	The contents of the unopened containers will maintain sterility for 180 days.	Same	<ul style="list-style-type: none"> <li>When sterilized by prevacuum steam sterilization, the Quad-Lock® Containers maintain the sterility of the contents for up to 180 days during storage and transport within the healthcare facility, as long as the integrity of the container has not been compromised</li> <li>When sterilized by ethylene oxide or low temperature hydrogen peroxide cycle types the Quad-Lock® Containers maintain the sterility of the contents when sterilized by any of the above for up to 30 days during storage and transport within the healthcare facility, as long as the integrity of the container has not been compromised</li> </ul> <p>New modalities have been validated to demonstrate efficacy. No new issues are raised due to these differences.</p>																				
Reuse	The container may be used up to 100 sterilization cycles	Same	Same																				
Sterilization Modality	Steam	Same	Steam, Ethylene Oxide, and Low Temperature Hydrogen Peroxide. New modalities have been validated to demonstrate efficacy. No new issues are raised due to these																				

<b>Table 3</b>			
<b>Substantial Equivalence Comparison</b>			
<b>Similarities and Differences</b>	<b>Predicate Symmetry Surgical Quad-Lock® Container Systems (Previously Codman)</b>	<b>Predicate Symmetry Surgical Quad-Lock® Container Systems (Previously Codman)</b>	<b>Proposed Symmetry Surgical Quad-Lock® Container Systems</b>
			differences.

### **Non-Clinical Performance Testing**

The intention of this Traditional 510(k) is to expand the cleared Indications for Use for the Symmetry Surgical Quad-Lock® Container. The device has been previously cleared for steam sterilization. Testing has been completed and supports the safety and effectiveness of the Quad-Lock® Container to support the system for expanded indications using EtO and low temperature H<sub>2</sub>O<sub>2</sub> sterilization modalities. The following table summarizes the performance testing that has been completed for each sterilization modality that has been added:

<b>Summary of Performance Testing</b>		
<b>Tests Performed</b>	<b>Description</b>	<b>Results</b>
Sterilization efficacy and simulated use testing	Validated sterility assurance level of 10 <sup>-6</sup>	Pass
Shelf life of sterile container	Maintenance of sterility after 30 days of storage	Pass
Reuse Testing	Microbial Challenge following multiple sterilization cycles verified for up to 100 sterilization cycles	Pass
Biocompatibility, extractables, and leachables	<i>In vitro</i> evaluations for these tests had acceptable results	Pass
Functional strength of handles	Testing performed in accordance with ST77 had acceptable results	Pass

### **Clinical Performance Testing**

The intention of this Traditional 510(k) is to expand the cleared Indications for Use for the Symmetry Surgical Quad-Lock® Container Systems. The Codman Quad-Lock Sterilization Container Systems were originally cleared by the FDA under 510(k) K092437 and K120117. There were no Clinical Tests performed.

### **Statement of Substantial Equivalence**

Based on the intended use, indications for use, technological characteristics, performance data and nonclinical tests performed the Symmetry Surgical Quad-Lock® Container Systems are substantially equivalent to the predicate devices, Codman™ Sterilization Containers (K092437 and K120117).