May 9, 2019

Synthes (USA) Products LLC / DePuy Orthopaedics Inc.
Thomas Shea
Manager Regulatory Affairs
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K181933
Trade/Device Name: DePuy Synthes Sterilization Container System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: April 8, 2019
Received: April 9, 2019

Dear Thomas Shea:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 David Krause, PhD
Acting 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: 06/30/2020

510(k) Number *(if known)*

K181933

Device Name

DePuy Synthes Sterilization Container System

Indications for Use *(Describe)*

The DePuy Synthes Sterilization Container System is a device intended to be used to enclose other medical devices to be sterilized by healthcare facilities. It allows sterilization of the enclosed medical devices and maintains sterility of the devices until used for a maximum of 180 days.

The containers are suitable for dynamic air removal (pre-vacuum) steam sterilization when used according to the instructions for use.

Sterilization Parameters and Devices Recommended for Use with System

Sterilization Parameters for the DePuy Synthes Sterilization Container Applicable to both Solid and Perforated Base Containers with Lifting Platforms			
Sterilization Method	**Cycle Parameters**	**Total System Weight**	**Devices and Materials Validated for Use with DePuy Synthes Containers**
Dynamic Air Removal (Pre-Vacuum) Steam	Exposure Temperature: 270°F (132°C) Pre-Conditioning Pulses: 3 Exposure Time: 4 Minutes Minimum Dry Time Cycle: 30 Minutes Minimum Cool Time: 60 minutes (may vary according to load contents) Stacking Containers During Sterile Processing Not Permitted.	Maximum 25 lbs. (Container plus contents)	Orthopaedic Medical Devices including Lumen (Cannulated) Devices. Mated Surface Devices (Devices or Device Configurations with conjoined surfaces which meet, touch or unite). Instrument and implant Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C.
Examples of device types with conjoined or mated surfaces include: forceps, clamps, bending pliers, and cable or plate cutters. Lumen devices include cannulated drill bits, guides, screwdrivers and cannulated screws; dead end lumen (Ø1.13mm x 50mm, Ø2.1mm x 330mm); Open end lumens (Ø0.3048mm x 5.5626mm, Ø0.9mm x 278mm, Ø1.1mm x 285mm, Ø3.65mm x 465mm, Ø4.5mm x 438mm).			

Examples of intrinsically stable metals include stainless steel, titanium (CP and alloys) and aluminum. Examples of thermoplastic polymers are PEEK, PEKK, PEI (Ultem), Acetal (Delrin), Radel (PPSU), Nylon, PTFE, Polypropylene, ABS (Acrylonitrile Butadiene Styrene) and POM (Polyoxymethylene).
Examples of thermosetting polymers are Phenolic and Silicone.
Examples of composites include carbon fiber reinforced epoxy (CFRE).

DePuy Synthes Sterilization Container and Accessory Configurations Supported by Validation Data		
Modality	**Dynamic Air Removal (Pre-Vacuum) Steam**	
Type of Container	**Contents / Configuration**	**Validation Details**
Perforated Base Container and Solid Base Container	Lifting Platform	Yes
	Dead end lumen: Ø1.13mm x 50mm	Yes
	Dead end lumen: Ø2.1mm x 330mm	Yes
	Open end lumen: Ø0.3048mm x 5.5626mm	Yes
	Open end lumen: Ø0.9mm x 278mm	Yes
	Open end lumen: Ø1.1mm x 285mm	Yes
	Open end lumen: Ø3.65mm x 465mm	Yes
	Open end lumen: Ø4.5mm x 438mm	Yes
	Mated Surfaces	Yes
	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C.	Yes
	Filter	62.010.002
	Data Card	62.010.005
	Tamper Evident Arrow	62.010.004
	Maximum Total Weight (Container plus Contents)	25 lbs.
	Stacking Containers During Sterile Processing	Not permitted
NOTE: This list refers to parameters of validated devices only. Please refer to the DePuy Synthes Sterilization Container System User Manual for further details on the validated and compatible products.		

Device Models and Accessories:

Container Descriptions and Dimensions					
Part Number	Description	Volume to Vent Ratio (in^3/in^2)	Weight (lbs.)	Outer Dimensions (L x W x H), in.	Inner Dimensions (L x W x H), in.
Perforated Bottom Containers					
62.006.001	Full-One Level, Perforated Base	26	8.5	23.1 x 12.4 x 4.5	21.0 x 11.4 x 4.2
62.006.002	Full-Two Level, Perforated Base	31	8.8	23.1 x 12.4 x 5.3	21.0 x 11.4 x 5.1
62.006.003	Full-Three Level, Perforated Base	42	9.4	23.1 x 12.4 x 7.0	21.0 x 11.4 x 6.8
62.009.004	Extended-Four Level, Perforated Base	56	9.7	25.2 x 12.4 x 8.5	23.0 x 11.4 x 8.4
62.009.005	Extended-Five Level, Perforated Base	63	10.3	25.2 x 12.4 x 9.5	23.0 x 11.4 x 9.4
Solid Bottom Containers					
62.016.001	Full-One Level, Solid Base	52	7.8	23.1 x 12.4 x 4.5	21.0 x 11.4 x 4.2
62.016.002	Full-Two Level, Solid Base	62	7.9	23.1 x 12.4 x 5.3	21.0 x 11.4 x 5.1
62.016.003	Full-Three Level, Solid Base	83	8.5	23.1 x 12.4 x 7.0	21.0 x 11.4 x 6.8
62.019.004	Extended-Four Level, Solid Base	112	9.1	25.2 x 12.4 x 8.5	23.0 x 11.4 x 8.4
62.019.005	Extended-Five Level, Solid Base	126	10.0	25.2 x 12.4 x 9.5	23.0 x 11.4 x 9.4
Lifting Platforms					
62.006.010	Lifting Platform for Full Container	N/A	2.6	20.5 x 10.6 x 1.3	N/A
62.009.010	Lifting Platform for Extended Container	N/A	2.9	22.5 x 10.6 x 1.3	N/A

Additional Items in DePuy Synthes Sterilization Container System	
Part Number	Description
Consumables	
62.010.002	Filters (1,000 pcs)
62.010.004	Tamper Evident Arrows (1,000 pcs)
62.010.005	Data Cards (500 pcs)
Replacement Parts	
Lids	
62.006.020	Lid for Full Sterilization Container
62.009.021	Lid for Extended Sterilization Container
Bases	
62.006.031	Perforated Base for Full-One Level Container
62.006.032	Perforated Base for Full-Two Level Container
62.006.033	Perforated Base for Full-Three Level Container
62.009.034	Perforated Base for Extended-Four Level Container
62.009.035	Perforated Base for Extended-Five Level Container
62.016.031	Solid Base for Full-One Level Container
62.016.032	Solid Base for Full-Two Level Container
62.016.033	Solid Base for Full-Three Level Container
62.019.034	Solid Base for Extended-Four Level Container
62.019.035	Solid Base for Extended-Five Level Container
Filter Retention Plates	
62.010.001	Optional Protective Plate
62.010.003	Filter Retention Plate, Top
62.010.006	Filter Retention Plate, Bottom

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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FORM FDA 3881 (7/17)

K181933 510(k) Summary

Sponsor	DePuy Synthes Thomas Shea 1301 Goshen Parkway West Chester, PA USA Phone: 610-719-5679
510(k) Number	K181933
Date Prepared	May 3, 2019
Proprietary Name	DePuy Synthes Sterilization Container System
Classification Name	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Classification	Class II Regulation Number: 21 CFR 880.6850 Product Code: KCT
Predicate Device	Synthes Reusable Sterilization Container System (K130720)
Reason for Submission	To support compatibility of the system with DePuy Synthes Joint Reconstruction Devices.
Device Description	The DePuy Synthes Reusable Sterilization Container System is a rigid, reusable, container intended to be used to sterilize other medical devices and maintain sterility of these devices until used. The container system is comprised of a lid with gasket, base, filter, tamper evident arrows, and data cards. The container system includes a lifting platform to hold Synthes graphic cases containing orthopedic medical devices (instruments and implants) within the container.
Indications for use	See below for the complete indications for use.
Contraindications	N/A

Indications for Use

The DePuy Synthes Sterilization Container System is a device intended to be used to enclose other medical devices to be sterilized by healthcare facilities. It allows sterilization of the enclosed medical devices and maintains sterility of the devices until used for a maximum of 180 days.

The containers are suitable for dynamic air removal (pre-vacuum) steam sterilization when used according to the instructions for use.

Sterilization Parameters and Devices Recommended for Use with System

Sterilization Parameters for the DePuy Synthes Sterilization Container Applicable to both Solid and Perforated Base Containers with Lifting Platforms			
Sterilization Method	**Cycle Parameters**	**Total System Weight**	**Devices and Materials Validated for Use with DePuy Synthes Containers**
Dynamic Air Removal (Pre-Vacuum) Steam	Exposure Temperature: 270°F (132°C) Pre-Conditioning Pulses: 3 Exposure Time: 4 Minutes Minimum Dry Time Cycle: 30 Minutes Minimum Cool Time: 60 minutes (may vary according to load contents) Stacking Containers During Sterile Processing Not Permitted.	Maximum 25 lbs. (Container plus contents)	Orthopaedic Medical Devices including Lumen (Cannulated) Devices. Mated Surface Devices (Devices or Device Configurations with conjoined surfaces which meet, touch or unite). Instrument and implant Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C.
Examples of device types with conjoined or mated surfaces include: forceps, clamps, bending pliers, and cable or plate cutters. Lumen devices include cannulated drill bits, guides, screwdrivers and cannulated screws; dead end lumen (Ø1.13mm x 50mm, Ø2.1mm x 330mm); Open end lumen (Ø0.3048mm x 5.5626mm, Ø0.9mm x 278mm, Ø1.1mm x 285mm, Ø3.65mm x 465mm, Ø4.5mm x 438mm). Examples of intrinsically stable metals include stainless steel, titanium (CP and alloys) and aluminum. Examples of thermoplastic polymers are PEEK, PEKK, PEI (Ultem), Acetal (Delrin), Radel (PPSU), Nylon, PTFE, Polypropylene, ABS (Acrylonitrile Butadiene Styrene) and POM (Polyoxymethylene). Examples of thermosetting polymers are Phenolic and Silicone. Examples of composites include carbon fiber reinforced epoxy (CFRE).			

DePuy Synthes Sterilization Container and Accessory Configurations Supported by Validation Data		
Modality	**Dynamic Air Removal (Pre-Vacuum) Steam**	
Type of Container	**Contents / Configuration**	**Validation Details**
Perforated Base Container and Solid Base Containers	Lifting Platform	Yes
	Dead end lumen: Ø1.13mm x 50mm	Yes
	Dead end lumen: Ø2.1mm x 330mm	Yes
	Open end lumen: Ø0.3048mm x 5.5626mm	Yes
	Open end lumen: Ø0.9mm x 278mm	Yes
	Open end lumen: Ø1.1mm x 285mm	Yes
	Open end lumen: Ø3.65mm x 465mm	Yes
	Open end lumen: Ø4.5mm x 438mm	Yes
	Mated Surfaces	Yes
	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C.	Yes
	Filter	62.010.002
	Data Card	62.010.005
	Tamper Evident Arrow	62.010.004
	Maximum Total Weight (Container plus Contents)	25 lbs.
	Stacking Containers During Sterile Processing	Not permitted
NOTE: This list refers to parameters of validated devices only. Please refer to the DePuy Synthes Sterilization Container System User Manual for further details on the validated and compatible products.		

Device Models and Accessories

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Lifting Platforms					
62.006.010	Lifting Platform for Full Container	N/A	2.6	20.5 x 10.6 x 1.3	N/A
62.009.010	Lifting Platform for Extended Container	N/A	2.9	22.5 x 10.6 x 1.3	N/A

Additional Items in DePuy Synthes Sterilization Container System	
Part Number	Description
Consumables	
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62.010.004	Tamper Evident Arrows (1,000 pcs)
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62.009.035	Perforated Base for Extended-Five Level Container
62.016.031	Solid Base for Full-One Level Container
62.016.032	Solid Base for Full-Two Level Container
62.016.033	Solid Base for Full-Three Level Container
62.019.034	Solid Base for Extended-Four Level Container
62.019.035	Solid Base for Extended-Five Level Container
Filter Retention Plates	
62.010.001	Optional Protective Plate
62.010.003	Filter Retention Plate, Top
62.010.006	Filter Retention Plate, Bottom

Technological Characteristics Comparison

Element	K181933 - Subject Device DePuy Synthes Sterilization Container System	K130720 - Predicate Device Synthes Reusable Sterilization Container System
Regulation	Regulation Number: 21 CFR 880.6850 Regulation Name: Sterilization Wrap Regulation Class; II Product Code: KCT	Regulation Number: 21 CFR 880.6850 Regulation Name: Sterilization Wrap Regulation Class; II Product Code: KCT
Intended Use	The DePuy Synthes Sterilization Container System is a device intended to be used to enclose other medical devices to be sterilized by healthcare facilities. It allows sterilization of the enclosed medical devices and maintains sterility of the devices until used for a maximum of 180 days. The containers are suitable for dynamic air removal (pre-vacuum) steam sterilization when used according to the instructions for use.	The Synthes Reusable Sterilization Container System is a device intended to be used to enclose other medical devices to be sterilized by a healthcare provider. It allows sterilization of the enclosed medical devices and maintains sterility of the devices until used for a maximum of 180 days. Synthes containers are suitable for dynamic air removal (pre-vacuum) steam sterilization when used according to the instructions for use. Reusable lifting platforms are intended to hold enclosed medical devices above the filter areas of a perforated bottom container during sterilization and storage of the container. Data cards are used to record information regarding a specific sterilization process load. Filter media allows ingress and egress of sterilant while providing a microbial barrier. Tamper evident arrows provide a visual indication that the container system has not been inadvertently opened prior to use. Each arrow contains a modality-specific (pre-vacuum steam) external process indicator that serves as a visual indication that the system has been exposed to a specific sterilization cycle parameter. Data cards, filters and tamper evident arrows are single use only.
General Device Description	Identical to predicate.	The Synthes Reusable Sterilization Container System is a rigid, reusable, container intended to be used to sterilize other

Element	K181933 - Subject Device DePuy Synthes Sterilization Container System	K130720 - Predicate Device Synthes Reusable Sterilization Container System
		Synthes medical devices and maintain sterility of these devices until used. The container system is comprised of a lid with gasket, base, filter, tamper evident arrows, and data cards. The container system includes a lifting platform to hold Synthes graphic cases containing orthopedic medical devices (instruments and implants) within the container.
Intended Sterilization Cycle	Identical to predicate.	Pre-vacuum Steam: Exposure Temperature: 270°F (132°C) Pre-Conditioning Pulses: 3 Exposure Time: 4 Minutes
Maximum Load Weight	Identical to predicate.	25 lbs. (Container plus Contents)
Material Composition	Identical to predicate.	Stainless Steel, Aluminum, Silicone (Gasket), SMS Polypropylene (Filter). The materials used in the construction of the containers do not degrade and have proven compatibility with the sterilization process and sterilants for which the system is indicated.
Physical Properties	Identical to predicate.	Anodized aluminum container with a secure latching system that seals the lid to the base with a gasket running along the perimeter. Aluminum retention plates secure single use SMS Polypropylene filters in place over ventilation holes in the lid and/or base of the container. The materials of construction have been demonstrated to withstand repeated processing according to reuse and sterilization modality parameters described in the IFU.
Chemical Properties	Identical to predicate.	Manufactured from aluminum, stainless steel, closed cell silicone foam, SMS polypropylene.
Configurations/ Dimensions	Identical to the predicate. Refer to the table on page 4 for the dimensions of all subject container models offered.	Solid or perforated base with perforated lid. Container sizes range from 23.1 x 12.4 x 4.5 to 25.2 x 12.4 x 9.5.

Element	K181933 - Subject Device DePuy Synthes Sterilization Container System	K130720 - Predicate Device Synthes Reusable Sterilization Container System
Air Permeance	Identical to predicate.	The predicate devices have perforated lids and bottoms and employ an SMS Polypropylene filter to allow ingress of sterilant.
Percent of Surface Perforations	Identical to predicate.	The volume to vent ratio (V:V, in^3/in^2) represents the total container volume divided by the total vent area. The V:V ratios for the proposed Synthes containers range from 26 – 126 in^3/in^2.
Sterilant Penetration	Lethality testing using worst case configuration of Joint Reconstruction devices for half-cycle lethality validation demonstrated all test samples were negative for growth. Identical to the predicate.	Lethality testing using over-challenge half-cycle lethality validation demonstrated all test samples were negative for growth.
Microbial Barrier Properties (Package Integrity)	Identical to predicate.	Whole package integrity/microbial barrier aerosol challenge demonstrated all containers tested passed and were 100% negative for growth when subjected to aerosol challenge testing.
Biocompatibility	Identical to predicate.	Biocompatibility testing of the materials of construction and colorants consisted of skin sensitivity, cytotoxicity and heavy metals leaching and determined the containers to be toxicologically acceptable for their intended use.
Shelf Life	Identical to predicate.	180 Day shelf life demonstrated by real time event related Shelf Life/Package Integrity testing.
Drying Time	30 Minute Minimum Dry Time supported by validation study utilizing worst case configuration of Joint Reconstruction devices and standard pre-vacuum steam cycle. Identical to the predicate.	30 Minute Minimum Dry Time supported by validation study utilizing worst case instrument challenge and standard pre-vacuum steam cycle.
Aeration Time	N/A – System not indicated for EO Sterilization	N/A – System not indicated for EO Sterilization

Non-Clinical Testing Summary			
Properties	**Standard/Test/FDA Guidance**	**Objective**	**Results Summary**
Sterilization Efficacy: Pre-Vacuum Steam	ANSI/AAMI ST77:2006 Containment Devices for Reusable Medical Device Sterilization.	To validate the efficacy of the DePuy Synthes Sterilization Container System using pre-vacuum sterilization cycle of 270°F (132°C) with 4 minutes of exposure.	Testing demonstrated a 12 log reduction and a sterility assurance level (SAL) of 10^{-6} using the biological (BI) overkill method and half-cycle validation.
Dry Time	ANSI/AAMI ST77:2006 Containment Devices for Reusable Medical Device Sterilization. ANSI/AAMI ST79:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.	To determine the drying time for the DePuy Synthes Sterilization Container System following a steam pre-vacuum cycle of 270°F (132°C) with 4 minutes of exposure.	Dry time studies establish minimum dry time of 30 minutes for pre-vacuum steam sterilization modality.
180 Day Event Related Shelf Life	ANSI/AAMI ST77:2006 Containment Devices for Reusable Medical Device Sterilization.	To validate the 180-day event related shelf life evaluation of the DePuy Synthes Sterilization Container System following exposure to a full pre-vacuum sterilization cycle (lethality plus dry time).	180 Day Event Related Shelf life studies demonstrated sterility maintenance for the recommended pre-vacuum steam sterilization modality.
Microbial Challenge	ANSI/AAMI ST77:2006 Containment Devices for Reusable Medical Device Sterilization.	To demonstrate the DePuy Synthes Sterilization Container System can maintain package integrity/microbial barrier after being subjected to sterilization processing and a whole package microbial (aerosol) challenge.	Whole package microbial challenge test, exposing a container to a minimum of 1×10^{-6} *Bacillus atrophaeus* colony forming units (CFU) via an aerosol challenge demonstrating 100% negative growth.
Limits of Reuse	Premarket Notification 510(k) Submissions for Medical Device Sterilization Systems in Health Care Facilities	To verify the limits of reuse of the DePuy Synthes Sterilization Container System when processed in repetitive pre-cleanings, mechanical washer cycles and steam pre-vacuum cycles.	After 100 cycles of processing samples showed no signs of physical or mechanical degradation and continued to function as intended.
Biocompatibility	USP General Chapter <231> Heavy Metals, Method I and Cytotoxicity according to ISO 10993-5, 2009	To evaluate the biocompatibility of the DePuy Synthes Sterilization Container System for cytotoxicity to mammalian cells in culture by a method compliant with the requirements specified in ISO 10993-5:2009	Results showed no heavy metal leaching or cytotoxicity at detectable levels.

Summary of Clinical Tests Conducted for Determination of Substantial Equivalence
N/A – No clinical tests were conducted for this submission.

Conclusion
The nonclinical testing performed demonstrates that the DePuy Synthes Sterilization Container System is as safe, as effective, and performs as well as or better than the legally marketed device the Synthes Reusable Sterilization Container System (K130720).