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

August 14, 2014

Synthes USA
Mr. Thomas Shea
Senior Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, PA 19380

Re: K130720
Trade/Device Name: Synthes Reusable Sterilization Container Systems
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Container
Regulatory Class: II
Product Code: KCT
Dated: July 16, 2014
Received: July 17, 2014

Dear Mr. 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. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Mary S. Runner -S

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

4.0 Indications for Use Statement

510(k): K130720

Device Name: Synthes Reusable Sterilization Container System

Indications 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.

Sterilization Parameters for the Synthes Reusable Sterilization Container			
Sterilization Method	**Cycle Parameters**	**Total System Weight**	**Containers, Accessories & Validated Contents**
Dynamic Air Removal (Pre-Vacuum) Steam	Exposure Temperature: 270°F (132°C) Pre-Conditioning Pulses: 3 Exposure Time: 4 Minutes Dry Time Cycle: 30 Minutes Minimum Cool Time: 60 minutes (may vary according to load contents) Stacking Not Permitted	25 lbs.	Solid Bottom Containers; Perforated Bottom Containers; Lifting Platforms. Lumen (Cannulated) Devices. Devices or Device Configurations with conjoined surfaces which meet, touch or unite. Mated surfaces. 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. 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).			

Synthes Reusable Sterilization Container and Accessory Configurations Supported by Validation Data		
Modality	**Dynamic Air Removal (Pre-Vacuum) Steam**	
Type of Container	**Contents / Configuration**	**Validation Details**
Perforated Bottom Container and Solid Bottom Container	Lifting Platform	Yes
	Dead end lumen: Ø2.1mm x 330mm	Yes
	Open end lumens: Ø0.9mm x 278mm	Yes
	Open end lumens: Ø1.1mm x 285mm	Yes
	Open end lumens: Ø1.35mm x 278mm	Yes
	Open end lumens: Ø3.65mm x 465mm	Yes
	Open end lumens: 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	NST Series
	Data Card	MD1-1
	Tamper Evident Arrow	AS2-3
	Maximum Total Weight (Container plus Contents)	25 lbs.
	Stacking	Not permitted

Synthes Reusable Sterilization Container Descriptions and Dimensions					
Synthes Part Number	Synthes Part 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	Not Applicable	2.6	20.5 x 10.6 x 1.3	Not Applicable
62.009.010	Lifting Platform for Extended Container	Not Applicable	2.9	22.5 x 10.6 x 1.3	Not Applicable

Additional Items in System	
Part Number	Description
Consumables	
DST-3	Filters (1,000/Box)
AS2-3	Tamper Evident Arrows (1,000/Box)
MD1-1	Data Cards (500/Box)
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
Additional Parts	
62.010.100	Identification Tag

Synthes Reusable Sterilization Container Compatibility, Contents, Accessories and Maximum Allowable Weight						
Container	**Lid**	**Compatible Graphic Case Footprint**	**Graphic Case Dimensions (L x W x H), in.**	**Contents**	**Required Accessories**	**Max. Weight (loaded)**
Full-One Level, Perforated or Solid Base	Full Size	Half length, 1 high	10.5 x 9.8 x 2.0	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C. Devices: Graphic Cases, Orthopedic Surgical Instruments, Implants Device Design Features: Mated Surfaces; Dead end lumen (Ø2.1mm x 330mm); Open end lumens (Ø0.9mm x 278mm) (Ø1.1mm x 285mm), (Ø1.35mm x 278mm), (Ø3.65mm x 465mm), (Ø4.5mm x 438mm)	2 Filters (Solid Base) 4 Filters (Perf. Base) Lifting Platform Tamper Evident Arrow	25 lb. (11.3 kg)
		2/3 length, 1 high	13.9 x 9.8 x 2.0			
		Full length, 1 high	20.7 x 9.8 x 2.0			
Full-Two Level, Perforated or Solid Base	Full Size	Half length, 2 high	10.5 x 9.8 x 3.4	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C. Devices: Graphic Cases, Orthopedic Surgical Instruments, Implants Device Design Features: Mated Surfaces; Dead end lumen (Ø2.1mm x 330mm); Open end lumens ((Ø0.9mm x 278mm) (Ø1.1mm x 285mm), (Ø1.35mm x 278mm), (Ø3.65mm x 465mm), (Ø4.5mm x 438mm)	2 Filters (Solid Base) 4 Filters (Perf. Base) Lifting Platform Tamper Evident Arrow	25 lb. (11.3 kg)
		2/3 length, 2 high	13.9 x 9.8 x 3.4			
		Full length, 2 high	20.7 x 9.8 x 3.4			
Full-Three Level, Perforated or Solid Base	Full Size	Half length, 3 high	10.5 x 9.8 x 4.9	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C. Devices: Graphic Cases, Orthopedic Surgical Instruments, Implants Device Design Features: Mated Surfaces; Dead end lumen (Ø2.1mm x 330mm); Open end lumens (Ø0.9mm x 278mm) (Ø1.1mm x 285mm), (Ø1.35mm x 278mm), (Ø3.65mm x 465mm), (Ø4.5mm x 438mm)	2 Filters (Solid Base) 4 Filters (Perf. Base) Lifting Platform Tamper Evident Arrow	25 lb. (11.3 kg)
		2/3 length, 3 high	13.9 x 9.8 x 4.9			
		Full length, 3 high	20.7 x 9.8 x 4.9			
Extended-Four Level, Perforated or Solid Base	Extended	Half length, 4 high	10.5 x 9.8 x 6.3	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use	2 Filters (Solid Base) 4 Filters (Perf. Base) Lifting Platform	25 lb. (11.3 kg)

DePuy Synthes
COMPANIES OF Johnson & Johnson

Synthes Reusable Sterilization Container Compatibility, Contents, Accessories and Maximum Allowable Weight						
Container	**Lid**	**Compatible Graphic Case Footprint**	**Graphic Case Dimensions (L x W x H), in.**	**Contents**	**Required Accessories**	**Max. Weight (loaded)**
		2/3 length, 4 high	13.9 x 9.8 x 6.3	temperatures above 135°C. Devices: Graphic Cases, Orthopedic Surgical Instruments, Implants Device Design Features: Mated Surfaces; Dead end lumen (Ø2.1mm x 330mm); Open end lumens (Ø0.9mm x 278mm) (Ø1.1mm x 285mm), (Ø1.35mm x 278mm), (Ø3.65mm x 465mm), (Ø4.5mm x 438mm)	Tamper Evident Arrow	
		Full length, 4 high	20.7 x 9.8 x 6.3			
Extended-Five Level, Perforated or Solid Base	Extended	Half length, 5 high	10.5 x 9.8 x 7.8	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C. Devices: Graphic Cases, Orthopedic Surgical Instruments, Implants Device Design Features: Mated Surfaces; Dead end lumen (Ø2.1mm x 330mm); Open end lumens (Ø0.9mm x 278mm) (Ø1.1mm x 285mm), (Ø1.35mm x 278mm), (Ø3.65mm x 465mm), (Ø4.5mm x 438mm)	2 Filters (Solid Base) 4 Filters (Perf. Base) Lifting Platform Tamper Evident Arrow	25 lb. (11.3 kg)
		2/3 length, 5 high	13 .9 x 9.8 x 7.8			
		Full length, 5 high	20.7 x 9.8 x 7.8			

Prescription Use _____ AND/OR Over-The-Counter Use_____X____

(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5.0 510(k) Summary – K130720

The following is a summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

Sponsor Information	
Name	Synthes
Address	1302 Wrights Lane East, West Chester, PA 19380
Phone	610-719-5679
FAX	484-356-9682
Establishment Registration	3008812563
Contact Person	Thomas N. Shea
Date Prepared	August 1, 2014
Device Information	
Proprietary Name	Synthes Reusable Sterilization Container System
Common Name	Sterilization Container
Device	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Regulation Description	Sterilization Wrap
Classification/Review Panel	80 General Hospital
Product Code	KCT
Submission Type	Traditional 510(k)
Regulation	880.6850
Device Class	Class II
Predicate Device	Genesis Reusable Rigid Sterilization Container System (**K112535)**
Reason for Submission	Introduction of a Synthes sterilization container for use with Synthes orthopedic medical devices.
Device Description	The Synthes Reusable Sterilization Container System is a rigid, reusable, container intended to be used to sterilize other 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.

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
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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
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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 System	
Part Number	Description
Consumables	
DST-3	Filters (1,000/Box)
AS2-3	Tamper Evident Arrows (1,000/Box)
MD1-1	Data Cards (500/Box)
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
Additional Parts	
62.010.100	Identification Tag

Comparison with Predicate Device:

Element	K130720 - Subject Device Synthes Reusable Sterilization Container System	K112535 – Predicate Genesis Reusable Rigid Sterilization Container System
Intended 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.	The Genesis Reusable Rigid Sterilization Container System is a device intended to be used t6 enclose another medical device that is to be sterilized by a healthcare provider. It allows sterilization of the enclosed medical device· and maintains sterility of the enclosed device until used for a maximum of 180 days. Containers are suitable for dynamic air removal (pre-vacuum) steam sterilization, immediate use pre-vacuum steam sterilization and 100% ethylene oxide sterilization when used as described in the instructions for use. Reusable baskets and accessory items (pins, dividers, mats, etc.) are intended to organize and secure enclosed medical devices 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 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.
Material Composition	Stainless Steel, Aluminum, Silicone (Gasket), SMS Polypropylene (Filter). All components in the subject system are identical in material composition to the predicate. The subject system does not contain polymeric components to hold devices within the container.	Stainless Steel, Aluminum, Silicone (Gasket), Silicone Elastomer (Bars, Mats, Instrument Holders), SMS Polypropylene (Filter), Radel/Polyphenysulfone/Aluminum/ Silicone Elastomer/Stainless (Laproscopic Instrument Racks).

Element	K130720 - Subject Device Synthes Reusable Sterilization Container System	K112535 – Predicate Genesis Reusable Rigid Sterilization Container System
Physical Properties	Physical properties of the subject container system are identical to the predicated. The sole difference is the color of the lid and branding. The colorization is done according to the same process as the predicate device.	The predicate consists of an 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	The material formulation, manufacturing process, chemical composition and steam sterilization modality for the proposed device is identical to the predicate device. The subject system does not include the polymeric components used to organize devices within the predicate container.	The predicate system is manufactured from aluminum, stainless steel, closed cell silicone foam, SMS polypropylene, and silicone polymeric components.
Configurations/ Dimensions	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, please see the table on the previous page for the dimensions of all subject container models offered.	Solid or perforated base with perforated lid. Container sizes cleared under K112535 range from 10.2 x 7.2 x 3.2 (smallest) to 28.1 x 11.2 x 6.4 (max length) 26.5 x 17.0 x 6.9 (max width) 19.2 x 12.5 x 9.4 (max depth).
Air Permeance	The subject container also has perforated lids and bottoms that feature the same size and amount of vent holes and makes use of the same filter as the predicate device (SMS Polypropylene) and will have the same permeability to allow ingress of sterilant.	The predicate container has perforated lids and bottoms and employs an SMS Polypropylene filter to allow ingress of sterilant.
Percent of Surface Perforations	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. All of the proposed containers fall within the range of volume to vent ratios for the predicate device.	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 predicate containers (K120535) range from 24 – 182 in^3/in^2.
Performance	**Subject Device**	**Predicate**
Sterilant Penetration	Lethality testing via over-challenge half-cycle lethality validation demonstrated all test samples were negative for growth following the seven (7) day incubation period,	Lethality testing via over-challenge half-cycle lethality validation demonstrated all test samples were negative for growth following the seven (7) day incubation period.

Element	K130720 - Subject Device Synthes Reusable Sterilization Container System	K112535 – Predicate Genesis Reusable Rigid Sterilization Container System
	identical to the predicate.	
Microbial Barrier Properties (Package Integrity)	Whole package integrity/microbial barrier aerosol challenge demonstrated all containers tested passed and were 100% negative for growth when subjected to aerosol challenge testing. Identical to the 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.
Material Compatibility	The subject container system is manufactured from the same materials as the predicate device and it's compatibility with the sterilization process is identical to the predicate.	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.
Toxicological Properties (Biocompatibility, including Sterilant Residue Limits)	No patient contact, contact with devices that will have external communicating, tissue/bone/dentin contact (limited exposure). The subject Container System will include a stainless steel lifting platform that represents the only internal component to hold devices within the container. The lifting platform is manufactured from type 304 stainless steel that conforms to ASTM Standard F899 and has an established biocompatibility profile. The system will not include the polymeric components, such as silicone bars or brackets that are included in the predicate system. The proposed system is indicated for prevacuum steam sterilization only therefore sterilant residues will not pose any risk to the patient. The material formulation, manufacturing process, chemical composition, body contact, and steam sterilization modality of the proposed device is equivalent to the predicate device.	No patient contact, contact with devices that will have external communicating, tissue/bone/dentin contact (limited exposure). Primary dermal irritation testing was performed on polymeric components of the container system. All samples were subjected to ISO Skin Irritation Testing (2 extracts – 0.9% Sodium Chloride and Sesame Oil Extracts) in compliance with the requirements noted in ISO 10993-10. These polymeric components were evaluated for biocompatibility and are considered to be toxicologically acceptable for their intended use.
Shelf Life	180 Day shelf life identical to the 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 device challenge identical to the predicate.	30 Minute Minimum Dry Time supported by validation study utilizing worst case instrument challenge.
Aeration Time	N/A – System not indicated for EO Sterilization	8 hours at 109.4°F (43°C) supported by 100% Ethylene Oxide Aeration Residual validation study

Summary of Technological Characteristics of the Subject Device In Comparison to the Predicate Device		
Characteristic	**Proposed Device Synthes Reusable Sterilization Container**	**Predicate Genesis Reusable Rigid Sterilization Container System (K112535)**
Container	Anodized Aluminum	Anodized Aluminum 5000 and 1100 Series; Stainless Steel 300 Series
Gasket	Closed Cell Silicone Foam	Closed Cell Silicone Foam
Filter Material	SMS Polypropylene for Pre-Vacuum Steam modality	SMS Polypropylene for all modalities
Lifting Platform/Basket	Lifting Platform 304 Stainless Steel Electropolished	Basket 304 Stainless Steel Electropolished
Dividers Brackets	N/A	Aluminum 5000 Series
Clips, Posts, Pins	N/A	300 & 400 Series Stainless
Silicone Bars, Mats	N/A	Silicone Elastomer

Performance Data		
Summary of Non-Clinical Testing Conducted for Determination of Substantial Equivalence		
Performance Test Summary - Proposed Device		
Characteristic	**Standard/Test/ FDA Guidance**	**Results Summary**
Sterilization Efficacy: Pre-Vacuum Steam	ANSI/AAMI ST77:2006 Containment Devices for Reusable Medical Device Sterilization.	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.	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.	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.	Whole package microbial challenge test, exposing a container to a minimum of 1 x 10^{-6} *Bacillus atrophaeus* colony forming units (CFU) via an aerosol challenge demonstrating 100% negative growth.

Summary of Clinical Tests Conducted for Determination of Substantial Equivalence
N/A – No clinical tests were conducted for this submission.
Conclusion
Information presented supports substantial equivalence of the Synthes Reusable Sterilization Container System to the predicate device based on similarities in intended use, design, principles of operation, and performance specifications. Sterilization Efficacy / Lethality testing was conducted on the proposed sterilization container system to support substantial equivalence to the predicate device and demonstrate effectiveness when used with Synthes orthopedic medical devices. Filter material properties, package integrity testing and 180 day shelf life validation are exactly the same as the predicate device. The performance testing data demonstrates that the Synthes Reusable Sterilization Container meet the same criteria as the predicate device is substantial equivalent.

Sterilization Parameters for the Synthes Reusable Sterilization Container Applicable to both Solid Bottom and Perforated Bottom Containers with Lifting Platforms			
Sterilization Method	**Cycle Parameters**	**Total System Weight**	**Types of Medical Devices & Materials Validated for Use**
Dynamic Air Removal (Pre-Vacuum) Steam	Exposure Temperature: 270°F (132°C) Pre-Conditioning Pulses: 3 Exposure Time: 4 Minutes Dry Time Cycle: 30 Minutes Minimum Cool Time: 60 minutes (may vary according to load contents) Stacking Not Permitted	25 lbs. (Container plus contents)	Orthopedic Medical Devices including Lumen (Cannulated) Devices. Devices or Device Configurations with conjoined surfaces which meet, touch or unite. Mated Surfaces. 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. 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).			

Synthes Reusable Sterilization Container System & Accessories Supported by Validation Data		
Modality	**Dynamic Air Removal (Pre-Vacuum) Steam**	
Type of Container	**Contents / Configuration**	**Validation Details**
Perforated Bottom Container and Solid Bottom Container	Lifting Platform	Yes
	Dead end lumen: Ø2.1mm x 330mm	Yes
	Open end lumens: Ø0.9mm x 278mm	Yes
	Open end lumens: Ø1.1mm x 285mm	Yes
	Open end lumens: Ø1.35mm x 278mm	Yes
	Open end lumens: Ø3.65mm x 465mm	Yes
	Open end lumens: 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	NST Series (SMS Polypropylene)
	Data Card	MD1-1
	Tamper Evident Arrow	AS2-3
	Maximum Total Weight (Container plus Contents)	25 lbs.
	Stacking	Not permitted

Container Compatibility, Contents, Accessories, Maximum Allowable Weight						
Container	**Lid**	**Compatible Graphic Case Footprint**	**Graphic Case Dimensions (L x W x H), in.**	**Contents**	**Required Accessories**	**Max. Weight (loaded)**
Full-One Level, Perforated or Solid Base	Full Size	Half length, 1 high	10.5 x 9.8 x 2.0	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C. Devices: Graphic Cases, Orthopedic Surgical Instruments, Implants Device Design Features: Mated Surfaces; Dead end lumen (Ø2.1mm x 330mm); Open end lumens (Ø0.9mm x 2.78mm) (Ø1.1mm x 285mm), (Ø1.35mm x 278mm), (Ø3.65mm x 465mm), (Ø4.5mm x 438mm)	2 Filters(Solid Base) 4 Filters (Perf. Base) Lifting Platform Tamper Evident Arrow	25 lb. (11.3 kg)
		2/3 length, 1 high	13.9 x 9.8 x 2.0			
		Full length, 1 high	20.7 x 9.8 x 2.0			
Full-Two Level, Perforated or Solid Base	Full Size	Half length, 2 high	10.5 x 9.8 x 3.4	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C. Devices: Graphic Cases, Orthopedic Surgical Instruments, Implants Device Design Features: Mated Surfaces; Dead end lumen (Ø2.1mm x 330mm); Open end lumens (Ø0.9mm x 2.78mm) (Ø1.1mm x 285mm), (Ø1.35mm x 278mm), (Ø3.65mm x 465mm), (Ø4.5mm x 438mm)	2 Filters(Solid Base) 4 Filters (Perf. Base) Lifting Platform Tamper Evident Arrow	25 lb. (11.3 kg)
		2/3 length, 2 high	13.9 x 9.8 x 3.4			
		Full length, 2 high	20.7 x 9.8 x 3.4			
Full-Three Level, Perforated or Solid Base	Full Size	Half length, 3 high	10.5 x 9.8 x 4.9	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C. Devices: Graphic Cases, Orthopedic Surgical Instruments, Implants Device Design Features: Mated Surfaces; Dead end lumen (Ø2.1mm x 330mm); Open end lumens (Ø0.9mm x 2.78mm) (Ø1.1mm x 285mm), (Ø1.35mm x 278mm), (Ø3.65mm x 465mm), (Ø4.5mm x 438mm)	2 Filters(Solid Base) 4 Filters (Perf. Base) Lifting Platform Tamper Evident Arrow	25 lb. (11.3 kg)
		2/3 length, 3 high	13.9 x 9.8 x 4.9			
		Full length, 3 high	20.7 x 9.8 x 4.9			

Container Compatibility, Contents, Accessories, Maximum Allowable Weight						
Container	**Lid**	**Compatible Graphic Case Footprint**	**Graphic Case Dimensions (L x W x H), in.**	**Contents**	**Required Accessories**	**Max. Weight (loaded)**
Extended-Four Level, Perforated or Solid Base	Extended	Half length, 4 high	10.5 x 9.8 x 6.3	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C. Devices: Graphic Cases, Orthopedic Surgical Instruments, Implants Device Design Features: Mated Surfaces; Dead end lumen (Ø2.1mm x 330mm); Open end lumens (Ø0.9mm x 2.78mm) (Ø1.1mm x 285mm), (Ø1.35mm x 278mm), (Ø3.65mm x 465mm), (Ø4.5mm x 438mm)	2 Filters(Solid Base) 4 Filters (Perf. Base) Lifting Platform Tamper Evident Arrow	25 lb. (11.3 kg)
		2/3 length, 4 high	13.9 x 9.8 x 6.3			
		Full length, 4 high	20.7 x 9.8 x 6.3			
Extended-Five Level, Perforated or Solid Base	Extended	Half length, 5 high	10.5 x 9.8 x 7.8	Materials: Intrinsically stable metals. Composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C. Devices: Graphic Cases, Orthopedic Surgical Instruments, Implants Device Design Features: Mated Surfaces; Dead end lumen (Ø2.1mm x 330mm); Open end lumens (Ø0.9mm x 2.78mm) (Ø1.1mm x 285mm), (Ø1.35mm x 278mm), (Ø3.65mm x 465mm), (Ø4.5mm x 438mm)	2 Filters(Solid Base) 4 Filters (Perf. Base) Lifting Platform Tamper Evident Arrow	25 lb. (11.3 kg)
		2/3 length, 5 high	13 .9 x 9.8 x 7.8			
		Full length, 5 high	20.7 x 9.8 x 7.8			