March 28, 2025

Synthes GmbH
Thomas Shea
Manger, Regulatory Affiars
Luzernstrasse 21
Zuchwil, SO 4528
Switzerland

Re: K241927
Trade/Device Name: Synthes Graphic Case & Tray System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: February 26, 2025
Received: February 26, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.03.28 16:08:45 -04'00'

for: Christopher Dugard
Director
DHT4C: Division of Infection Control
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241927

Device Name
Synthes Graphic Case & Tray System

Indications for Use *(Describe)*
The Synthes Graphic Case & Tray System are used in healthcare facilities to store, organize, and transport DePuy Synthes orthopedic instruments and implants during sterilization and surgical procedures. The Synthes Graphic Case & Tray System are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, FDA-cleared sterile barrier (e.g., wraps or reusable rigid sterilization containers).

The Synthes Graphic Case & Tray System is validated for use with orthopedic medical devices including lumen (cannulated) devices and mated surface devices (devices or device configurations with conjoined surfaces which meet, touch or unite). Compatible instrument and implant materials include intrinsically stable metals, composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C.

The Synthes Graphic Case & Tray System were validated for a maximum load of 25 lbs (case + contents+ lid+ weight of sterile barrier wrap).

Method: Steam Sterilization (Moist Heat Sterilization) Cycle Pre-vacuum
Temperature: 270 °F (132 °C)
Exposure time: 4 minutes
Minimum Drying time: 20 minutes

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Synthes Graphic Case & Tray System - Description and Dimensions				
Part Number	Part Description	Volume to Vent Ratio (in^3/in^2) (with Lid)	Weight (lbs.)	Dimensions (in) (L x W x H) Case/Tray (L x W) Lids
Outer Cases				
60.133.181	1 High, 1/3 width outer case	5.62	1.62	7.1 x 9.7 x 1.9
60.133.182	1 High, 2/3 width outer case	4.84	2.19	13.6 x 9.7 x 1.9
60.133.183	1 High, 3/3 width outer case	4.72	2.73	20 x 9.7 x 1.9
60.133.213	2 High, 1/3 width outer case	8.11	2.10	7.1 x 9.7 x 3.4
60.133.223	2 High, 2/3 width outer case	7.35	2.78	13.6 x 9.7 x 3.4
60.133.200	2 High, 3/3 width outer case	6.12	3.41	20 x 9.7 x 3.4
60.133.313	3 High, 1/3 width outer case	9.34	2.51	7.1 x 9.7 x 5
60.133.323	3 High, 2/3 width outer case	8.81	3.31	13.6 x 9.7 x 5
60.133.300	3 High, 3/3 width outer case	8.30	4.04	20 x 9.7 x 5
60.133.413	4 High, 1/3 width outer case	10.05	2.92	7.1 x 9.7 x 6.6
60.133.423	4 High, 2/3 width outer case	9.69	3.83	13.6 x 9.7 x 6.6
60.133.400	4 High, 3/3 width outer case	9.19	4.65	20 x 9.7 x 6.6
Case Lids				

Synthes Graphic Case & Tray System - Description and Dimensions				
Part Number	Part Description	Volume to Vent Ratio (in^3/in^2) (with Lid)	Weight (lbs.)	Dimensions (in) (L x W x H) Case/Tray (L x W) Lids
60.133.013	1/3 width lid	n/a	.60	7.1 x 9.7
60.133.023	2/3 width lid	n/a	1.01	13.6 x 9.7
60.133.000	3/3 width lid	n/a	1.59	20 x 9.7
Auxiliary Trays * Representative for all 1 high Tray size				
60.133.103	Auxiliary Tray 1/3 width	5.62	.89	6.34 x 9.25 x 1.77
60.133.169	Auxiliary Tray, 1 High, 2/3 Width	4.84	1.80	12.80 x 9.25 x 1.77
60.133.171	Auxiliary Tray, 1 High, 3/3 Width	4.72	2.70	19.25 x 9.25 x 1.77
Auxiliary Tray Lids				
60.133.111	Lid (1/3 Width), Aluminium Tray	n/a	0.81	6.61 x 9.65
60.133.110	Lid (2/3 Width), Aluminium Tray	n/a	1.33	13.07 x 9.65
60.133.109	Lid 3/3 Aluminium Tray	n/a	1.79	19.53 x 9.65'

510(k) Summary K241927

Sponsor	Synthes GmbH Luzernstrasse 21 4528 Zuchwil, Switzerland
Contact	Thomas Shea Manager, Regulatory Affairs T: +1 610-719-5679 E: tshea@its.jnj.com
Alternate Contact	Damon Lees Director, Regulatory Affairs T: +1 610-719-5608 E: dlees@its.jnj.com
Date Prepared	March 25, 2025
Proprietary Name	Synthes Graphic Case & Tray System
Classification Name	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Classification	Class II Regulation Number: 21 CFR 880.6850 Product Code: KCT
Predicate / Reference devices	Predicate Device: CrossRoads Tray System (K202268) Reference Device: DePuy Synthes Sterilization Container System (K181933)
Device Description	The Synthes Graphic Case and Tray System is a modular, reusable case and tray system intended for use in health care facilities for the purpose of containing medical devices for sterilization. It is composed of multiple pieces, designed to be integrated into a single unit that contains and protects instruments and implants during sterilization and transport. All components are perforated for steam penetration.
Indications for Use	The Synthes Graphic Case & Tray System are used in healthcare facilities to store, organize, and transport DePuy Synthes orthopedic instruments and implants during sterilization and surgical procedures. The Synthes Graphic Case & Tray System are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, FDA-cleared sterile barrier (e.g., wraps or reusable rigid sterilization containers). The Synthes Graphic Case & Tray System is validated for use with orthopedic medical devices including lumen (cannulated) devices and mated surface devices (devices or device configurations with conjoined surfaces which meet, touch or unite). Compatible instrument and implant materials include intrinsically stable metals, composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C. The Synthes Graphic Case & Tray System were validated for a maximum load of 25 lbs (case + contents+ lid+ weight of sterile barrier wrap). Method: Steam Sterilization (Moist Heat Sterilization) Cycle Pre-vacuum Temperature: 270 °F (132 °C) Exposure time: 4 minutes Minimum Drying time: 20 minutes

Synthes Graphic Case & Tray System - Description and Dimensions				
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Auxiliary Trays * Representative for all 1 high Tray size				
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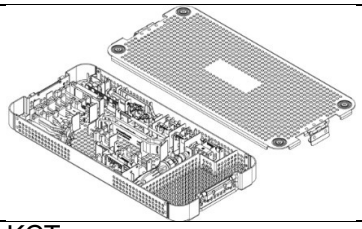
60.133.110	Lid (2/3 Width), Aluminium Tray	n/a	1.33	13.07 x 9.65
60.133.109	Lid 3/3 Aluminium Tray	n/a	1.79	19.53 x 9.65`

Technological Comparison

Presented below is a Technological Comparison covering the design and performance specifications of the subject device and the predicate.

Comparator	Subject Device (K241927)	Predicate Device (K202268)	Comparison
Device Name	Synthes Graphic Case and Tray System	CrossRoads Tray System	
Device Image			
Product Code	KCT	KCT	Same
Intended Use	The Synthes Graphic Case and Tray System is designed to hold surgical implants and instruments in order to organize, steam sterilize and transport the devices between uses. The cases and trays are intended to be wrapped with an FDA-cleared sterilization wrap or placed within a reusable sterilization container during the pre-vacuum autoclave sterilization process.	The CrossRoads Tray System is designed to hold various surgical instruments in order to organize, steam sterilize and transport the instruments between uses. The trays are wrapped with an FDA-cleared sterilization wrap during the pre-vacuum autoclave sterilization process.	Similar

Comparator	Subject Device (K241927)	Predicate Device (K202268)	Comparison
Indications for Use	The Synthes Graphic Case & Tray System is used in healthcare facilities to store, organize, and transport DePuy Synthes orthopedic instruments and implants during sterilization and surgical procedures. The Synthes Graphic Case & Tray System are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, FDA-cleared sterile barrier (e.g., wraps or reusable rigid sterilization containers). The Synthes Graphic Case & Tray System is validated for use with orthopedic medical devices including lumen (cannulated) devices and mated surface devices (devices or device configurations with conjoined surfaces which meet, touch or unite). Compatible instrument and implant materials include intrinsically stable metals, composites, thermoplastics and thermosetting polymers with constant use temperatures above 135°C. The Synthes Graphic Case & Tray System were validated for a maximum load of 25 lbs (case + contents+ lid+ weight of sterile barrier wrap). Method: Steam Sterilization (Moist Heat Sterilization) Cycle Pre-vacuum Temperature: 270 °F (132 °C) Exposure time: 4 minutes Minimum Drying time: 20 minutes	The CrossRoads Tray System is used in healthcare facilities to store and organize CrossRoads surgical instruments and components during cleaning/sterilization and during implant/prosthetic treatment. The CrossRoads Tray System are not intended on their own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization pouch or sterilization wrap. Sterilization validations for the worst-case CrossRoads Tray System included surgical instruments such as drills, inserters, reamers, fixation pin, benders, and ratcheting handles. The CrossRoads Tray System is validated for a maximum load of 8.5 lbs (tray + instruments). Method: Steam Sterilization (Moist Heat Sterilization) Cycle Pre-vacuum Temperature: 270 °F (132 °C) Exposure time: 4 minutes Drying time: 20 minutes The tray is 20.60” length x 9.80” width x 2.00” depth.	Different, subject device includes indications for device types and materials validated for use with the system.
Intended Device Load	Implants and instruments	Implants and instruments	Same
Max Weight	25 lbs (case + contents+ lid + weight of sterile barrier)	8.5 lbs (tray + instruments)	Different, subject system is validated for a greater max load
Materials	Lid/base– Aluminum Inserts – Silicone, Aluminum, Stainless Steel Latch – Stainless Steel	Lid/base/Lift out tray – Aluminum Inserts – Silicone, aluminum, stainless steel Latch – Stainless steel	Similar

Design	Outer case, inner tray, lids	Base and lid	Similar
Comparator	**Subject Device (K241927)**	**Predicate Device (K202268)**	**Comparison**
Dimensions	Cases and trays ranging in size from 7.2 – 20.1 length x 9.8 width x 1.8 – 6.5 inches depth See Table in IFU for complete list of cases and trays with dimensions.	20.60 length x 9.80 width x 2.00 inches depth	Different, subject system offers a range of sizes
Sterilization Parameters			
Sterilization Method	Pre-vacuum (steam)	Pre-vacuum (steam)	Same
Cycle Temperature	270°F (132°C)	270°F (132°C)	Same
Cycle Time	4 minutes	4 minutes	Same
Dry Time	20 minutes	20 minutes	Same
Sterile Barrier	FDA cleared sterilization wrap or rigid container	FDA cleared sterilization wrap or pouch	Similar
Performance Testing			
Non-clinical performance testing	Sterilization Efficacy Dry Time Cleaning Biocompatibility Durability (Limits of Reuse)	Sterilization Efficacy Dry Time Cleaning Biocompatibility	Similar

Non-clinical Testing Summary

Nonclinical testing included Sterilization Efficacy, Dry Time and Thermal Profiling, Manual and Automated Cleaning Validation, Biocompatibility, and Durability (Limits of Reuse). Testing demonstrates that the Synthes Graphic Case and Tray System is summarized in the table below.

Test	Purpose	Acceptance Criteria	Results
Sterilization Efficacy with FDA cleared sterilization wrap	Validation for the efficacy of the dynamic air removal steam sterilization process in attaining a sterility assurance level (SAL) of 10^{-6} via the overkill method using a half cycle for the Synthes Graphic Case and Tray System when processed in two layers of blue sterilization wrap.	• All biological indicator test samples shall be negative for growth of the indicator organism following the minimum incubation period. • The positive controls shall be positive for growth. • The negative and environmental controls should be negative for growth. • The Chemical Integrators shall demonstrate steam penetration. • The sterilizer cycle tapes shall verify that the specified parameters were achieved.	Pass, all acceptance criteria met. • Each product BI test location was negative for growth • Each positive control BI type was positive for growth • Each negative and environmental control BI type was negative for growth • All integrators demonstrated steam penetration • The sterilizer cycle tapes verified that the cycle parameters were achieved
Sterilization Efficacy with FDA cleared rigid sterilization container	Validation for the efficacy of the dynamic air removal steam sterilization process in attaining a sterility assurance level (SAL) of 10^{-6} via the overkill method using a half cycle for the Synthes Graphic Case and Tray System when processed in a rigid sterilization container.	• All biological indicator (BI) test samples shall be negative for growth of the indicator organism following the minimum incubation period. • The positive controls shall be positive for growth. • The negative and environmental controls should be negative for growth. • The Chemical Integrators shall demonstrate steam penetration. • The sterilizer cycle tapes shall verify that the specified parameters were achieved.	Pass, all acceptance criteria met. • Each product BI test location was negative for growth • Each positive control BI type was positive for growth • Each negative and environmental control BI type was negative for growth • All integrators demonstrated steam penetration • The sterilizer cycle tapes verified that the cycle parameters were achieved

Test	Purpose	Acceptance Criteria	Results
Dry Time and Thermal Profiling with FDA cleared sterilization wrap	Validation of the efficacy of thermal profile and dry time for the Synthes Graphic Case and Tray System when processed in a two layers of blue sterilization wrap.	• The system shall demonstrate an average pre- and post-sterilization weight difference of less than 0.2% within five (5) minutes of cycle completion. • The sample shall demonstrate no visible moisture present on the outside of the sample or on the instruments contained inside following the thirty (30) minute cooling period. • At the end of each cycle, the temperature sensors shall be found to have remained in position. • The internal temperature profiles shall demonstrate that the minimum sterilization cycle lethality value (F0) of 12.0 minutes is achieved at each of the product thermocouple locations during the dwell time (plateau) phase of the cycle. • The chemical integrators shall demonstrate steam penetration. • Cycle tapes shall confirm that the required cycle parameters were achieved for each cycle.	Pass, all acceptance criteria met. • For Autoclave Parameter of 20 Minute Dry Time: Cycle 1: -0.085% Cycle 2: 0.093% Cycle 3: 0.062% • For Autoclave Parameter of 20 Minute Dry Time: No Visible Moisture • At the end of the cycle, the temperature sensors were found to have remained in position. • F_0 results of >12.0 achieved for Cycle 1,2 and 3 for all locations • All integrators demonstrated steam penetration. • The sterilizer cycle tapes verified that the cycle parameters were achieved:

Test	Purpose	Acceptance Criteria	Results
Dry Time and Thermal Profiling with FDA cleared rigid sterilization container	Validation of the efficacy of thermal profile and dry time for the Synthes Graphic Case and Tray System when processed in a rigid sterilization container.	• The system shall demonstrate an average pre- and post-sterilization weight difference of less than 0.2% within five (5) minutes of cycle completion. • The sample shall demonstrate no visible moisture present on the outside of the sample or on the instruments contained inside following the thirty (30) minute cooling period. • At the end of each cycle, the temperature sensors shall be found to have remained in position. • The internal temperature profiles shall demonstrate that the minimum sterilization cycle lethality value (F0) of 12.0 minutes is achieved at each of the product thermocouple locations during the dwell time (plateau) phase of the cycle. • The chemical integrators shall demonstrate steam penetration. • Cycle tapes shall confirm that the required cycle parameters were achieved for each cycle.	Pass, all acceptance criteria met. Pass, all acceptance criteria met. • For Autoclave Parameter of 20 Minute Dry Time: Cycle 1: 0.00% Cycle 2: 0.00% Cycle 3: 0.00% Cycle 4: 0.00% Cycle 5: 0.00% Cycle 6: 0.00% • For Autoclave Parameter of 20 Minute Dry Time: No Visible Moisture • At the end of the cycle, the temperature sensors were found to have remained in position. • F_0 results of >12.0 achieved for all cycles and for all locations • All integrators demonstrated steam penetration. • The sterilizer cycle tapes verified that the cycle parameters were achieved

Test	Purpose	Acceptance Criteria	Results
Cleaning (Manual)	To validate the manual cleaning method, the device challenge features present in the Case and Tray System were soiled with a clinically relevant soil for orthopedic surgery, cleaned using worst case process parameters (e.g. times, water temperature, and/or cleaning solution concentration) and analyzed for the presence of two clinically relevant analytes, protein and hemoglobin.	• The extraction efficiency shall be greater than or equal to 70%. • Test samples show no visible soil after cleaning. • The overall result of the protein analyte test is a level of < 6.4µg / cm^2. This is calculated by adding the standard deviation of the sample results to the highest individual result. • The overall result of the hemoglobin analyte test is a level of < 2.2µg / cm^2. This is calculated by adding the standard deviation of the sample results to the highest individual result.	• The extraction efficiency was greater than or equal to 70% at each sample location. • There was no visible soil after cleaning. • For all cycles the acceptance criteria were met with an observed protein analyte level of < 6.4µg / cm^2. • For all cycles the acceptance criteria were met with an observed hemoglobin analyte test is a level of < 2.2µg / cm^2.
Cleaning (Automated)	To validate the automated cleaning method, the device challenge features present in the Case and Tray System were soiled with a clinically relevant soil for orthopedic surgery, cleaned using worst case process parameters (e.g. times, water temperature, and/or cleaning solution concentration) and analyzed for the presence of two clinically relevant analytes, protein and hemoglobin.	• The extraction efficiency shall be greater than or equal to 70%. • Test samples show no visible soil after cleaning. • The overall result of the protein analyte test is a level of < 6.4µg / cm^2. This is calculated by adding the standard deviation of the sample results to the highest individual result. • The overall result of the hemoglobin analyte test is a level of < 2.2µg / cm^2. This is calculated by adding the standard deviation of the sample results to the highest individual result.	• The extraction efficiency was greater than or equal to 70% at each sample location. • There was no visible soil after cleaning. • For all cycles the acceptance criteria was met with an observed protein analyte level of < 6.4µg / cm^2. • For all cycles the acceptance criteria were met with an observed hemoglobin analyte test is a level of < 2.2µg / cm^2.

Test	Purpose	Acceptance Criteria	Results
Biocompatibility assessment (ANSI/AAMI/ISO 10993-5:2009 – Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity)	The biocompatibility testing evaluated the materials of construction (aluminum, stainless steel and silicone) as well as the silkscreen inks and anodization dyes used to print graphics and text on the cases and trays, to ensure no cell toxic substances will be transferred to the medical devices contained within the case or tray during processing.	Pass is a score of less than 2.	There was no cytotoxic reaction observed (Grade 0) any of the sample extracts.
Durability (Limits of Reuse)	The objective of this evaluation was to verify the limits of reuse (durability) of the subject device, Synthes Graphic Case and Tray System. The testing was intended to demonstrate that the subject devices can withstand repeated clinical reprocessing cycles (i.e., mechanical washer cycles and steam pre-vacuum sterilization cycles) without unacceptable effects occurring to the material, joints, surfaces, color, labeling, function, etc. which could compromise patient / user safety or product's function during its intended lifetime.	After 100 cycles of clinical processing the subject device should show no signs of damage and continue to function properly. Damage, including but not limited to: • Corrosion (e.g. rust, pitting), • Fading or discoloration of artwork or labeling that which product cannot be identified • Scratches • Flaking of anodized surfaces • Cracks and wear • Bent lid corners near the latching features • Burs or sharp edges around the perimeter that may tear sterile barrier materials Proper function, including but not limited to: • Bending of flexible devices, • Movement of hinges / joint / box locks and moveable features such as handles, ratcheting and couplings. • Sticky or jammed latch or handles when opening and closing	All acceptance criteria were met and the results demonstrate that the subject devices continue to function as intended and after 104 clinical reprocessing cycles.

Clinical testing was not necessary for the determination of substantial equivalence.

Conclusion:
The conclusions drawn from the nonclinical testing demonstrate that the subject device, Synthes Graphic Case and Tray System, is as safe, as effective, and performs as well as or better than the legally marketed predicate device.