



February 26, 2026

DePuy Mitek, Inc.
Jeffrey Dzialo
Senior Regulatory Affairs Specialist
325 Paramount Dr.
Raynham, Massachusetts 02767

Re: K253791

Trade/Device Name: PUREVUE™ Quick Connect Cannula System Tray; PUREVUE™ Quick
Connect Cannula System Lid

Regulation Number: 21 CFR 880.6850

Regulation Name: Sterilization wrap

Regulatory Class: Class II

Product Code: KCT

Dated: November 26, 2025

Received: November 28, 2025

Dear Jeffrey Dzialo:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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. Digitally signed by
ANISKO -S STEPHEN A. ANISKO -S
Date: 2026.02.26
11:43:35 -05'00'

Stephen Anisko
Acting Assistant Director
DHT4C: Division of Infection
Control Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K253791

Device Name

PUREVUE™ Quick Connect Cannula System Tray and PUREVUE™ Quick Connect Cannula System Lid

Indications for Use (Describe)

The PUREVUE™ Quick Connect Cannula System Tray and PUREVUE™ Quick Connect Cannula System Lid are used to store, organize, and transport PUREVUE™ Quick Connect Cannula System instruments during sterilization and surgical procedures. The tray and lid 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 wrap.

The tray and lid were validated for a maximum load of 22.1 lb (tray + contents + lid + wrap).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

Table 1 includes validated stem sterilization (moist heat sterilization) cycle parameters.

Table 1: Validated Steam Sterilization Cycle Parameters.

Method	Exposure Time (minutes)	Exposure Temperature	Minimum Drying Time (minutes)
Pre-vacuum Steam Sterilization Cycle	4	132 °C (270°F)	30 to 60
Pre-vacuum Steam Sterilization Cycle	3	134 °C (274°F)	30 to 60

Table 2 includes information regarding the descriptions and dimensions of the tray and lid.

Table 2: Descriptions and Dimensions of PUREVUE™ Quick Connect Cannula System Tray and PUREVUE™ Quick Connect Cannula System Lid.

Part Number	Part Description	Volume to Vent Ratio (in ³ /in ²) (with Lid)	Weight (lb)	Dimensions (in) (L x W x H) Tray (L x W) Lid
242333	PUREVUE™ Quick Connect Cannula System Tray	10.08	4.73	21.23 x 9.71 x 2.86
242334	PUREVUE™ Quick Connect Cannula System Lid	Not applicable	1.81	21.50 x 10.01 x 0.63

510(k) Summary K253791

Submitter's Name and Address	DePuy Mitek, Inc. 325 Paramount Drive Raynham, MA 02767, USA <i>On behalf of:</i> Medos International SARL Chemin-Blanc 38 CH-2400 Le Locle Switzerland
Contact Person	Jeffrey Dzialo Senior Regulatory Affairs Specialist Phone: +1 800-382-4682 Email: jdzialo@its.jnj.com
Alternate Contact	Pol Fort Grèbol Project Manager Regulatory Affairs Phone: +34 672-672-579 Email: pfortgre@its.jnj.com
Date Prepared	February 25, 2026
Proprietary Name	PUREVUE™ Quick Connect Cannula System Tray PUREVUE™ Quick Connect Cannula System Lid
Common Name	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Regulation Number	21 CFR § 880.6850 (Sterilization wrap)
Regulatory Class	Class II
Product Code	KCT
Predicate Device	Synthes Graphic Case & Tray System (K241927) No reference devices were used in this submission.
Device Description Summary	The PUREVUE™ Quick Connect Cannula System Tray and PUREVUE™ Quick Connect Cannula System Lid are a modular, reusable tray and lid system intended for use in health care facilities for the purpose of containing medical devices for sterilization. The system is composed of two pieces, designed to be integrated into a single unit that contains and protects PUREVUE™ Quick Connect Cannula System instruments during sterilization and transport. All components are perforated for steam penetration.

<p>Intended Use</p>	<p>The PUREVUE™ Quick Connect Cannula System Tray and PUREVUE™ Quick Connect Cannula System Lid are intended to hold PUREVUE™ Quick Connect Cannula System instruments during the sterilization process, storage, and transportation between uses.</p>																											
<p>Indications for Use</p>	<p>The PUREVUE™ Quick Connect Cannula System Tray and PUREVUE™ Quick Connect Cannula System Lid are used to store, organize, and transport PUREVUE™ Quick Connect Cannula System instruments during sterilization and surgical procedures. The tray and lid 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 wrap.</p> <p>The tray and lid were validated for a maximum load of 22.1 lb (tray + contents + lid + wrap).</p> <p>Table 1 includes validated steam sterilization (moist heat sterilization) cycle parameters.</p> <p>Table 1: Validated Steam Sterilization Cycle Parameters.</p> <table border="1" data-bbox="495 982 1421 1150"> <thead> <tr> <th>Method</th> <th>Exposure Time (minutes)</th> <th>Exposure Temperature</th> <th>Minimum Drying Time (minutes)</th> </tr> </thead> <tbody> <tr> <td>Pre-vacuum Steam Sterilization Cycle</td> <td>4</td> <td>132 °C (270°F)</td> <td>30 to 60</td> </tr> <tr> <td>Pre-vacuum Steam Sterilization Cycle</td> <td>3</td> <td>134 °C (274°F)</td> <td>30 to 60</td> </tr> </tbody> </table> <p>Table 2 includes information regarding the descriptions and dimensions of the tray and lid.</p> <p>Table 2: Descriptions and Dimensions of PUREVUE™ Quick Connect Cannula System Tray and PUREVUE™ Quick Connect Cannula System Lid.</p> <table border="1" data-bbox="495 1390 1421 1726"> <thead> <tr> <th>Part Number</th> <th>Part Description</th> <th>Volume to Vent Ratio (in³/in²) (with Lid)</th> <th>Weight (lb)</th> <th>Dimensions (in) (L x W x H) Tray (L x W) Lid</th> </tr> </thead> <tbody> <tr> <td>242333</td> <td>PUREVUE™ Quick Connect Cannula System Tray</td> <td>10.08</td> <td>4.73</td> <td>21.23 x 9.71 x 2.86</td> </tr> <tr> <td>242334</td> <td>PUREVUE™ Quick Connect Cannula System Lid</td> <td>Not applicable</td> <td>1.81</td> <td>21.50 x 10.01 x 0.63</td> </tr> </tbody> </table>	Method	Exposure Time (minutes)	Exposure Temperature	Minimum Drying Time (minutes)	Pre-vacuum Steam Sterilization Cycle	4	132 °C (270°F)	30 to 60	Pre-vacuum Steam Sterilization Cycle	3	134 °C (274°F)	30 to 60	Part Number	Part Description	Volume to Vent Ratio (in ³ /in ²) (with Lid)	Weight (lb)	Dimensions (in) (L x W x H) Tray (L x W) Lid	242333	PUREVUE™ Quick Connect Cannula System Tray	10.08	4.73	21.23 x 9.71 x 2.86	242334	PUREVUE™ Quick Connect Cannula System Lid	Not applicable	1.81	21.50 x 10.01 x 0.63
Method	Exposure Time (minutes)	Exposure Temperature	Minimum Drying Time (minutes)																									
Pre-vacuum Steam Sterilization Cycle	4	132 °C (270°F)	30 to 60																									
Pre-vacuum Steam Sterilization Cycle	3	134 °C (274°F)	30 to 60																									
Part Number	Part Description	Volume to Vent Ratio (in ³ /in ²) (with Lid)	Weight (lb)	Dimensions (in) (L x W x H) Tray (L x W) Lid																								
242333	PUREVUE™ Quick Connect Cannula System Tray	10.08	4.73	21.23 x 9.71 x 2.86																								
242334	PUREVUE™ Quick Connect Cannula System Lid	Not applicable	1.81	21.50 x 10.01 x 0.63																								
<p>Indications for Use Comparison</p>	<p>The subject and predicate devices share comparable intended use, indications for use, intended user, and user training requirements. The minor differences in the intended use statements primarily reflect the distinct formatting approaches adopted by DePuy Mitek, Inc. and</p>																											

	Synthes. These variations are negligible and do not raise new questions of safety or effectiveness.			
Comparison of Technological Characteristics with the Predicate Device	The subject devices, PUREVUE™ Quick Connect Cannula System Tray and PUREVUE™ Quick Connect Cannula System Lid, are compared to the previously cleared Synthes Graphic Case & Tray System (K241927) regarding intended use, indications for use, technological characteristics (design features), and operating principle.			
	Characteristic	Subject Devices (K253791)	Predicate Device (K241927)	Comparison
	General Information			
	Proprietary Name	(1) PUREVUE™ Quick Connect System Tray (2) PUREVUE™ Quick Connect System Lid	(1) Synthes Graphic Case & Tray System	Not applicable
	Representative Image (Tray)			Similar
	Representative Image (Lid)			Similar
	Product Code	Same as the predicate device.	KCT	Same
	Intended Use			
	Intended Use	The PUREVUE™ Quick Connect Cannula System Tray and PUREVUE™ Quick Connect Cannula System Lid are intended to hold PUREVUE™ Quick Connect Cannula System instruments during the sterilization process, storage, and transportation between uses.	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.	Similar. The predicate device can be used with both instruments and surgical implants, and is qualified for use with a rigid sterilization container.
	Indications for Use	The PUREVUE™ Quick Connect Cannula System Tray and PUREVUE™ Quick Connect	The Synthes Graphic Case & Tray System is used in healthcare facilities to store, organize, and	Similar. The predicate device is validated for a greater maximum load and the subject

		<p>Cannula System Lid are used to store, organize, and transport PUREVUE™ Quick Connect Cannula System instruments during sterilization and surgical procedures. The tray and lid 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 wrap.</p> <p>The tray and lid were validated for a maximum load of 22.1 lb (tray + contents + lid + wrap).</p> <p>Table 1 includes validated steam sterilization (moist heat sterilization) cycle parameters.</p> <table border="1" data-bbox="730 1123 933 1176"> <caption>Table 1: Validated Steam Sterilization Cycle Parameters</caption> <thead> <tr> <th>Method</th> <th>Exposure Time (minutes)</th> <th>Exposure Temperature (°C/°F)</th> <th>Minimum D₁₀ (2.00/0.25)</th> </tr> </thead> <tbody> <tr> <td>Pre-sterilization Cycle</td> <td>4</td> <td>132 °C (270 °F)</td> <td>20 x 30</td> </tr> <tr> <td>Post-sterilization Cycle</td> <td>2</td> <td>133 °C (271 °F)</td> <td>20 x 30</td> </tr> </tbody> </table> <p>Table 2: Descriptions and Dimensions of PUREVUE™ Quick Connect Cannula System Tray and PUREVUE™ Quick Connect Cannula System Lid.</p> <table border="1" data-bbox="730 1459 933 1543"> <caption>Table 2: Descriptions and Dimensions of PUREVUE™ Quick Connect Cannula System Tray and PUREVUE™ Quick Connect Cannula System Lid</caption> <thead> <tr> <th>Part Number</th> <th>Part Description</th> <th>Volume of Sterile Instrument (L)</th> <th>Weight (lb)</th> <th>Dimensions (L x W x H) (mm)</th> </tr> </thead> <tbody> <tr> <td>DC203</td> <td>PUREVUE™ Quick Connect Cannula System Tray</td> <td>3.00</td> <td>4.75</td> <td>21.2 x 41.7 x 4.0</td> </tr> <tr> <td>DC204</td> <td>PUREVUE™ Quick Connect Cannula System Lid</td> <td>Not applicable</td> <td>1.81</td> <td>21.0 x 41.0 x 4.0</td> </tr> </tbody> </table>	Method	Exposure Time (minutes)	Exposure Temperature (°C/°F)	Minimum D ₁₀ (2.00/0.25)	Pre-sterilization Cycle	4	132 °C (270 °F)	20 x 30	Post-sterilization Cycle	2	133 °C (271 °F)	20 x 30	Part Number	Part Description	Volume of Sterile Instrument (L)	Weight (lb)	Dimensions (L x W x H) (mm)	DC203	PUREVUE™ Quick Connect Cannula System Tray	3.00	4.75	21.2 x 41.7 x 4.0	DC204	PUREVUE™ Quick Connect Cannula System Lid	Not applicable	1.81	21.0 x 41.0 x 4.0	<p>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).</p> <p>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.</p> <p>The Synthes Graphic Case & Tray System were validated for a maximum load of 25 lb (case + contents+ lid+ weight of sterile barrier wrap).</p> <table border="1" data-bbox="974 1701 1169 1753"> <caption>Identification Parameters</caption> <thead> <tr> <th>Parameter</th> <th>Value</th> </tr> </thead> <tbody> <tr> <td>Device</td> <td>Synthes Sterilization Sterile Item</td> </tr> <tr> <td>Cycle</td> <td>Pre-sterilization</td> </tr> <tr> <td>Temperature</td> <td>132°C (270°F)</td> </tr> <tr> <td>Exposure Time</td> <td>4 minutes</td> </tr> <tr> <td>Minimum D₁₀ Time</td> <td>20 minutes</td> </tr> </tbody> </table>	Parameter	Value	Device	Synthes Sterilization Sterile Item	Cycle	Pre-sterilization	Temperature	132°C (270°F)	Exposure Time	4 minutes	Minimum D ₁₀ Time	20 minutes	<p>devices include additional pre-vacuum sterilization cycle parameters.</p>
Method	Exposure Time (minutes)	Exposure Temperature (°C/°F)	Minimum D ₁₀ (2.00/0.25)																																								
Pre-sterilization Cycle	4	132 °C (270 °F)	20 x 30																																								
Post-sterilization Cycle	2	133 °C (271 °F)	20 x 30																																								
Part Number	Part Description	Volume of Sterile Instrument (L)	Weight (lb)	Dimensions (L x W x H) (mm)																																							
DC203	PUREVUE™ Quick Connect Cannula System Tray	3.00	4.75	21.2 x 41.7 x 4.0																																							
DC204	PUREVUE™ Quick Connect Cannula System Lid	Not applicable	1.81	21.0 x 41.0 x 4.0																																							
Parameter	Value																																										
Device	Synthes Sterilization Sterile Item																																										
Cycle	Pre-sterilization																																										
Temperature	132°C (270°F)																																										
Exposure Time	4 minutes																																										
Minimum D ₁₀ Time	20 minutes																																										

			<table border="1"> <thead> <tr> <th>Part Number</th> <th>Part Description</th> <th>Material</th> <th>Material</th> <th>Material</th> <th>Material</th> </tr> </thead> <tbody> <tr> <td>0000-0000</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>00101-001</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-002</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-003</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-004</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-005</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-006</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-007</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-008</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-009</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-010</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-011</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-012</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-013</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-014</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-015</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-016</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-017</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-018</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-019</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-020</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-021</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-022</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-023</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-024</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-025</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-026</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-027</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-028</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-029</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-030</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-031</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-032</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-033</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-034</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-035</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-036</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-037</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-038</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-039</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-040</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-041</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-042</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-043</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-044</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-045</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-046</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-047</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-048</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-049</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-050</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-051</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-052</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-053</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-054</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-055</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-056</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-057</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-058</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-059</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-060</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-061</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-062</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-063</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-064</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-065</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-066</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-067</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-068</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-069</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-070</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-071</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-072</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-073</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-074</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-075</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-076</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-077</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-078</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-079</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-080</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-081</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-082</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-083</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-084</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-085</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-086</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-087</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-088</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-089</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-090</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-091</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-092</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-093</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-094</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-095</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-096</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-097</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-098</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-099</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> <tr> <td>00101-100</td> <td>Tray, 11 well auto case</td> <td>304</td> <td>304</td> <td>316L</td> <td>316L</td> </tr> </tbody> </table>	Part Number	Part Description	Material	Material	Material	Material	0000-0000						00101-001	Tray, 11 well auto case	304	304	316L	316L	00101-002	Tray, 11 well auto case	304	304	316L	316L	00101-003	Tray, 11 well auto case	304	304	316L	316L	00101-004	Tray, 11 well auto case	304	304	316L	316L	00101-005	Tray, 11 well auto case	304	304	316L	316L	00101-006	Tray, 11 well auto case	304	304	316L	316L	00101-007	Tray, 11 well auto case	304	304	316L	316L	00101-008	Tray, 11 well auto case	304	304	316L	316L	00101-009	Tray, 11 well auto case	304	304	316L	316L	00101-010	Tray, 11 well auto case	304	304	316L	316L	00101-011	Tray, 11 well auto case	304	304	316L	316L	00101-012	Tray, 11 well auto case	304	304	316L	316L	00101-013	Tray, 11 well auto case	304	304	316L	316L	00101-014	Tray, 11 well auto case	304	304	316L	316L	00101-015	Tray, 11 well auto case	304	304	316L	316L	00101-016	Tray, 11 well auto case	304	304	316L	316L	00101-017	Tray, 11 well auto case	304	304	316L	316L	00101-018	Tray, 11 well auto case	304	304	316L	316L	00101-019	Tray, 11 well auto case	304	304	316L	316L	00101-020	Tray, 11 well auto case	304	304	316L	316L	00101-021	Tray, 11 well auto case	304	304	316L	316L	00101-022	Tray, 11 well auto case	304	304	316L	316L	00101-023	Tray, 11 well auto case	304	304	316L	316L	00101-024	Tray, 11 well auto case	304	304	316L	316L	00101-025	Tray, 11 well auto case	304	304	316L	316L	00101-026	Tray, 11 well auto case	304	304	316L	316L	00101-027	Tray, 11 well auto case	304	304	316L	316L	00101-028	Tray, 11 well auto case	304	304	316L	316L	00101-029	Tray, 11 well auto case	304	304	316L	316L	00101-030	Tray, 11 well auto case	304	304	316L	316L	00101-031	Tray, 11 well auto case	304	304	316L	316L	00101-032	Tray, 11 well auto case	304	304	316L	316L	00101-033	Tray, 11 well auto case	304	304	316L	316L	00101-034	Tray, 11 well auto case	304	304	316L	316L	00101-035	Tray, 11 well auto case	304	304	316L	316L	00101-036	Tray, 11 well auto case	304	304	316L	316L	00101-037	Tray, 11 well auto case	304	304	316L	316L	00101-038	Tray, 11 well auto case	304	304	316L	316L	00101-039	Tray, 11 well auto case	304	304	316L	316L	00101-040	Tray, 11 well auto case	304	304	316L	316L	00101-041	Tray, 11 well auto case	304	304	316L	316L	00101-042	Tray, 11 well auto case	304	304	316L	316L	00101-043	Tray, 11 well auto case	304	304	316L	316L	00101-044	Tray, 11 well auto case	304	304	316L	316L	00101-045	Tray, 11 well auto case	304	304	316L	316L	00101-046	Tray, 11 well auto case	304	304	316L	316L	00101-047	Tray, 11 well auto case	304	304	316L	316L	00101-048	Tray, 11 well auto case	304	304	316L	316L	00101-049	Tray, 11 well auto case	304	304	316L	316L	00101-050	Tray, 11 well auto case	304	304	316L	316L	00101-051	Tray, 11 well auto case	304	304	316L	316L	00101-052	Tray, 11 well auto case	304	304	316L	316L	00101-053	Tray, 11 well auto case	304	304	316L	316L	00101-054	Tray, 11 well auto case	304	304	316L	316L	00101-055	Tray, 11 well auto case	304	304	316L	316L	00101-056	Tray, 11 well auto case	304	304	316L	316L	00101-057	Tray, 11 well auto case	304	304	316L	316L	00101-058	Tray, 11 well auto case	304	304	316L	316L	00101-059	Tray, 11 well auto case	304	304	316L	316L	00101-060	Tray, 11 well auto case	304	304	316L	316L	00101-061	Tray, 11 well auto case	304	304	316L	316L	00101-062	Tray, 11 well auto case	304	304	316L	316L	00101-063	Tray, 11 well auto case	304	304	316L	316L	00101-064	Tray, 11 well auto case	304	304	316L	316L	00101-065	Tray, 11 well auto case	304	304	316L	316L	00101-066	Tray, 11 well auto case	304	304	316L	316L	00101-067	Tray, 11 well auto case	304	304	316L	316L	00101-068	Tray, 11 well auto case	304	304	316L	316L	00101-069	Tray, 11 well auto case	304	304	316L	316L	00101-070	Tray, 11 well auto case	304	304	316L	316L	00101-071	Tray, 11 well auto case	304	304	316L	316L	00101-072	Tray, 11 well auto case	304	304	316L	316L	00101-073	Tray, 11 well auto case	304	304	316L	316L	00101-074	Tray, 11 well auto case	304	304	316L	316L	00101-075	Tray, 11 well auto case	304	304	316L	316L	00101-076	Tray, 11 well auto case	304	304	316L	316L	00101-077	Tray, 11 well auto case	304	304	316L	316L	00101-078	Tray, 11 well auto case	304	304	316L	316L	00101-079	Tray, 11 well auto case	304	304	316L	316L	00101-080	Tray, 11 well auto case	304	304	316L	316L	00101-081	Tray, 11 well auto case	304	304	316L	316L	00101-082	Tray, 11 well auto case	304	304	316L	316L	00101-083	Tray, 11 well auto case	304	304	316L	316L	00101-084	Tray, 11 well auto case	304	304	316L	316L	00101-085	Tray, 11 well auto case	304	304	316L	316L	00101-086	Tray, 11 well auto case	304	304	316L	316L	00101-087	Tray, 11 well auto case	304	304	316L	316L	00101-088	Tray, 11 well auto case	304	304	316L	316L	00101-089	Tray, 11 well auto case	304	304	316L	316L	00101-090	Tray, 11 well auto case	304	304	316L	316L	00101-091	Tray, 11 well auto case	304	304	316L	316L	00101-092	Tray, 11 well auto case	304	304	316L	316L	00101-093	Tray, 11 well auto case	304	304	316L	316L	00101-094	Tray, 11 well auto case	304	304	316L	316L	00101-095	Tray, 11 well auto case	304	304	316L	316L	00101-096	Tray, 11 well auto case	304	304	316L	316L	00101-097	Tray, 11 well auto case	304	304	316L	316L	00101-098	Tray, 11 well auto case	304	304	316L	316L	00101-099	Tray, 11 well auto case	304	304	316L	316L	00101-100	Tray, 11 well auto case	304	304	316L	316L	
Part Number	Part Description	Material	Material	Material	Material																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
0000-0000																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																								
00101-001	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-002	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-003	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-004	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-005	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-006	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-007	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-008	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-009	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-010	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-011	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-012	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-013	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-014	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-015	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-016	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-017	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-018	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-019	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-020	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-021	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-022	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-023	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-024	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-025	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-026	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-027	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-028	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-029	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-030	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-031	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-032	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-033	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-034	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-035	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-036	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-037	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-038	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-039	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-040	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-041	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-042	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-043	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-044	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-045	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-046	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-047	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-048	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-049	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-050	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-051	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-052	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-053	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-054	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-055	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-056	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-057	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-058	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-059	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-060	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-061	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-062	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-063	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-064	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-065	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-066	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-067	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-068	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-069	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-070	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-071	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-072	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-073	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-074	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-075	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-076	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-077	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-078	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-079	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-080	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-081	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-082	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-083	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-084	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-085	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-086	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-087	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-088	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-089	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-090	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-091	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-092	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-093	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-094	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-095	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-096	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-097	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-098	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-099	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
00101-100	Tray, 11 well auto case	304	304	316L	316L																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
	Contraindications	Same as the predicate device.	There are no contraindications specific to these devices.	Same																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																				
Technological Characteristics																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																								
	Principles of Operation	The PUREVUE™ Quick Connect Cannula System Tray and PUREVUE™ Quick Connect System Lid consist of general, non-sterile, reusable sterilization cases intended to contain and organize instruments for sterile processing. All components are perforated to allow ingress and egress of steam during sterilization. The tray and lid facilitate storage, handling, and transport of instruments between uses.	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.	Same																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																				
	Device Features	<ul style="list-style-type: none"> • Basic lid/base design • General use trays • Perforated for steam sterilization • Handles • Latches 	<ul style="list-style-type: none"> • Basic lid/base design • General use trays • Perforated for steam sterilization • Handles • Latches 	Same																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																				

	Dimensions	<u>Range of Dimensions</u> <ul style="list-style-type: none"> Length: 21.23 inches to 21.50 inches Width: 9.71 inches to 10.01 inches Height: 0.63 inches to 2.86 inches <u>Total Validated System</u> <ul style="list-style-type: none"> Weight: 22.1 lb (container + contents + lid + wrap) 	<u>Range of Dimensions</u> <ul style="list-style-type: none"> Length: 6.34 inches to 20 inches Width: 9.25 inches to 9.7 inches Height: 1.77 inches to 6.6 inches <u>Total Validated System</u> <ul style="list-style-type: none"> Weight: 25 lb (container + contents + lid + wrap) 	Similar
	Compatible Devices	PUREVUE™ Quick Connect Cannula System instruments	DePuy Synthes Implants and Instruments	Similar
	Materials	<ul style="list-style-type: none"> Lid/base – Aluminum Inserts – Silicone, Aluminum, Stainless Steel Latch – Stainless Steel 	<ul style="list-style-type: none"> Lid/base – Aluminum Inserts – Silicone, Aluminum, Stainless Steel Latch – Stainless Steel 	Same
	Sterilization Method	Same as the predicate device.	Pre-vacuum Steam Sterilization Cycle	Same
	Cycle Temperature	The subject devices are validated for the same sterilization cycle as the predicate device. In addition, the subject devices are validated for a pre-vacuum cycle with a 3-minute exposure time at 134 °C (274°F).	270°F (132°C)	Similar. The subject devices include an additional cycle at 134 °C (274°F).
	Cycle Time	The subject devices are validated for the same sterilization cycle as the predicate device. In addition, the subject devices are validated for a pre-vacuum cycle with a 3-minute exposure time at 134 °C (274°F).	4 minutes	Similar. The subject devices include an additional cycle with 3-minute exposure time.
	Dry Time	30 minutes to 60 minutes	20 minutes	Similar

Sterile Barrier	The subject devices are intended to be used in conjunction with a legally marketed, FDA-cleared sterile barrier wrap.	FDA cleared sterilization wrap or rigid container.	Same. The predicate device is also qualified for use with a rigid container.
Patient Contact	Same as the predicate device.	No direct or indirect patient contact.	Same
Performance Data			
Non-clinical Performance Testing	<ul style="list-style-type: none"> • Steam Sterilization Efficacy • Dry Time Validation • Device Processing Cleaning Efficacy – Manual Cleaning • Device Processing Cleaning Efficacy – Automated (Mechanical) Cleaning • Durability Assessment (Limits of Reuse) • Biocompatibility (Cytotoxicity of Ink Test Coupon) • Design Verification for Tray/Lid Functional Testing 	<ul style="list-style-type: none"> • Steam Sterilization Efficacy • Dry Time Validation • Device Processing Cleaning Efficacy – Manual Cleaning • Device Processing Cleaning Efficacy – Automated (Mechanical) Cleaning • Durability Assessment (Limits of Reuse) • Biocompatibility (Cytotoxicity for Ink Test Coupon) 	Same. The subject devices include design verification functional testing.
<p>The subject and predicate devices utilize the same design characteristics and fundamental technology, as presented in the previous table. The subject and predicate devices are perforated trays and lids composed of anodized aluminum bases with aluminum, stainless steel, and silicon inserts, as well as stainless-steel latches. The subject devices are intended for the storage, organization, transport, and sterile processing of medical devices. The subject and predicate devices are not intended to maintain sterility on their own and are reliant on an FDA-cleared</p>			

	<p>sterile barrier. The subject and predicate devices share the same principles of operation, device features, materials, and sterilization method.</p> <p>The primary differences in technological characteristics (dimensions and weight) stem from the compatible devices which are intended to be sterilized within the container systems. The predicate case and tray system can be used with a broad set of instruments and implants, whereas the subject devices are utilized with the PUREVUE™ Quick Connect Cannula System instruments specifically. Because of the differences in compatible devices there are some differences in device dimensions and intended maximum weight. These differences are negligible as they did not result in unexpected design verification or validation results and are consistent with the respective intended use. In summary, all differences in technological characteristics have been identified and do not raise new questions of safety or effectiveness.</p>								
<p>Non-clinical and Clinical Performance Data</p>	<p>Design verification and validation testing were performed on the subject PUREVUE™ Quick Connect Cannula System Tray and PUREVUE™ Quick Connect Cannula System Lid as a result of the risk analysis and product requirements.</p> <p>Performance testing results were compared to those of the predicate device and demonstrated that the proposed devices are suitable for their intended use.</p> <p>Performance Testing</p> <p>Performance testing was conducted to ensure the device design meets user needs in the environment of use as shown in the table below.</p> <table border="1" data-bbox="495 1276 1421 1917"> <thead> <tr> <th data-bbox="495 1276 727 1394">Test Performed</th> <th data-bbox="727 1276 959 1394">Objective of the Test</th> <th data-bbox="959 1276 1192 1394">Pre-defined Acceptance Criteria</th> <th data-bbox="1192 1276 1421 1394">Results Summary</th> </tr> </thead> <tbody> <tr> <td data-bbox="495 1394 727 1917">Steam Sterilization Efficacy</td> <td data-bbox="727 1394 959 1917">The purpose of the testing was to validate the sterilization efficacy of the PUREVUE™ Quick Connect Cannula System Tray and Lid when wrapped and processed in a steam pre-vacuum sterilization cycle at 132°C (270°F) with four (4) minutes exposure time.</td> <td data-bbox="959 1394 1192 1917">All biological indicator test samples shall be negative for growth following the minimum incubation period. The positive controls shall be positive for growth. The negative and environmental controls shall be negative for growth. The Chemical Integrators shall demonstrate steam</td> <td data-bbox="1192 1394 1421 1917">The subject devices passed the acceptance criteria and met the requirements. The study results demonstrate the efficacy of the steam sterilization process in attaining a minimum microbiological lethality (F₀) of 12.0 minutes and therefore, achieving a Sterility Assurance Level (SAL) of 10⁻⁶ in the worst case set</td> </tr> </tbody> </table>	Test Performed	Objective of the Test	Pre-defined Acceptance Criteria	Results Summary	Steam Sterilization Efficacy	The purpose of the testing was to validate the sterilization efficacy of the PUREVUE™ Quick Connect Cannula System Tray and Lid when wrapped and processed in a steam pre-vacuum sterilization cycle at 132°C (270°F) with four (4) minutes exposure time.	All biological indicator test samples shall be negative for growth following the minimum incubation period. The positive controls shall be positive for growth. The negative and environmental controls shall be negative for growth. The Chemical Integrators shall demonstrate steam	The subject devices passed the acceptance criteria and met the requirements. The study results demonstrate the efficacy of the steam sterilization process in attaining a minimum microbiological lethality (F ₀) of 12.0 minutes and therefore, achieving a Sterility Assurance Level (SAL) of 10 ⁻⁶ in the worst case set
Test Performed	Objective of the Test	Pre-defined Acceptance Criteria	Results Summary						
Steam Sterilization Efficacy	The purpose of the testing was to validate the sterilization efficacy of the PUREVUE™ Quick Connect Cannula System Tray and Lid when wrapped and processed in a steam pre-vacuum sterilization cycle at 132°C (270°F) with four (4) minutes exposure time.	All biological indicator test samples shall be negative for growth following the minimum incubation period. The positive controls shall be positive for growth. The negative and environmental controls shall be negative for growth. The Chemical Integrators shall demonstrate steam	The subject devices passed the acceptance criteria and met the requirements. The study results demonstrate the efficacy of the steam sterilization process in attaining a minimum microbiological lethality (F ₀) of 12.0 minutes and therefore, achieving a Sterility Assurance Level (SAL) of 10 ⁻⁶ in the worst case set						

			<p>penetration.</p> <p>The sterilizer cycle tapes shall verify that the parameters per were achieved. were achieved.</p> <p>NOTE: In the event that a positive sample can clearly be identified as a source other than that of a sterilization efficacy failure, the sample shall be rendered invalid. Specifics to the cause of such a positive sample can be identified with a justification in the final report.</p>	<p>configuration container within the PUREVUE™ Quick Connect Cannula System Tray and Lid.</p>
	Dry Time Validation	<p>The purpose of the testing was to determine the proper drying time of the DePuy Synthes PUREVUE™ Quick Connect System (including the tray and lid) when processed in a hospital steam pre-vacuum sterilization cycle at 132°C (270°F) with four (4) minutes exposure time and 134°C (273°F) for 3 minutes exposure time.</p>	<p>The wrapped instrument case shall produce a pre- and post-sterilization weight difference of less than 0.2% within five (5) minutes of cycle completion.</p> <p>Each instrument tray of the case and sterilization wrap shall exhibit no visible moisture following thirty (20) minutes of cooling.</p> <p>The integrators shall demonstrate steam penetration.</p> <p>The cycle tapes shall confirm that the required cycle parameters were achieved.</p>	<p>The subject devices passed the acceptance criteria and met the requirements.</p>
	Device Processing Cleaning Efficacy – Manual Cleaning	<p>The purpose of the testing was to validate the manual cleaning procedure of the PUREVUE™ Quick Connect Cannula System (including the tray and lid).</p>	<p>Protein level shall be $\leq 6.4 \mu\text{g}/\text{cm}^2$.</p> <p>Hemoglobin level shall be $\leq 2.2 \mu\text{g}/\text{cm}^2$.</p> <p>Each test sample shall have no visible soil after cleaning.</p> <p>The extraction efficiency shall be</p>	<p>The subject devices passed the acceptance criteria and met the requirements.</p>

			<p>greater than or equal to 70%.</p> <p>The standard deviation of the sample set added to the concentration of the highest data point shall not exceed the acceptance criterion of 6.4 µg/cm².</p>	
	<p>Device Processing Cleaning Efficacy – Automated (Mechanical) Cleaning</p>	<p>The purpose of the testing was to validate the automated cleaning procedure of the PUREVUE™ Quick Connect Cannula System (including the tray and lid).</p>	<p>The study results shall validate that the manufacturer’s automated cleaning instructions are efficacious in removing gross amounts of soil from the DePuy Synthes PUREVUE™ Quick Connect Cannula System (including the tray and lid).</p> <p>Protein levels shall be less than 6.4 µg/cm².</p> <p>Hemoglobin levels shall be less than 2.2 µg/cm².</p>	<p>The subject devices passed the acceptance criteria and met the requirements.</p>
	<p>Durability Assessment (Limits of Reuse)</p>	<p>The purpose of the testing was to demonstrate that the subject devices can withstand repeated clinical reprocessing 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.</p>	<p>The PUREVUE™ Quick Connect Cannula System Tray shall have direct part markings identifying instrument profiles with instrument description</p> <p>The PUREVUE™ Quick Connect Cannula System Tray shall allow for insertion and removal of instruments without damage.</p> <p>The PUREVUE™ Quick Connect Cannula System Tray shall group 10 cannulas, 2 bridges, 6 obturators, and 1 switching stick, accommodating either length cannula</p>	<p>The subject devices passed the acceptance criteria and met the requirements.</p>

			<p>or obturator.</p> <p>The PUREVUE™ Quick Connect Cannula System Tray and Lid shall lock and unlock via side latch, forming a sterilization container.</p> <p>All products in scope shall meet the criteria of 500 reprocessing cycles.</p> <p>There shall be no observations of unacceptable damage, including but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks and wear, or illegible part markings post testing.</p> <p>The devices shall demonstrate proper function, including but not limited to, connection and functional fit.</p>	
	<p>Biocompatibility (Cytotoxicity for Ink Test Coupon)</p>	<p>The purpose of this study was to determine the potential of the Aluminum Coupon (Fujifilm Ink) test article to cause cytotoxicity.</p>	<p>The results of the testing shall show Grade ≤ 2 cytotoxicity (mildly reactive).</p>	<p>The subject devices passed the acceptance criteria and met the requirements.</p> <p>The test article extract showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).</p>
	<p>Design Verification for Tray/Lid Functional Testing</p>	<p>The objective of this testing was to establish evidence that the PUREVUE™ Quick Connect Cannula System Tray and Lid meet the form, fit, and functional</p>	<p>The PUREVUE™ Quick Connect Cannula System Tray and Lid shall meet the following pre-determined acceptance criteria:</p> <ul style="list-style-type: none"> • Dimensional 	<p>The subject devices passed the acceptance criteria and met the requirements.</p>

	<table border="1"> <tr> <td data-bbox="483 216 727 405"></td> <td data-bbox="727 216 959 405"> requirements outlined in the Requirements Traceability Matrix and mitigate associated risk. </td> <td data-bbox="959 216 1187 405"> <ul style="list-style-type: none"> • Functional fit • Visual • Loaded weight </td> <td data-bbox="1187 216 1432 405"></td> </tr> </table>		requirements outlined in the Requirements Traceability Matrix and mitigate associated risk.	<ul style="list-style-type: none"> • Functional fit • Visual • Loaded weight 	
	requirements outlined in the Requirements Traceability Matrix and mitigate associated risk.	<ul style="list-style-type: none"> • Functional fit • Visual • Loaded weight 			
	<p>Software Verification and Validation No software verification or validation testing was required or performed for the subject devices, as they do not incorporate software functions.</p> <p>Electrical Safety and Electromagnetic Compatibility (EMC) No electrical safety or EMC testing was required or performed for the subject devices, as they do not contain electrical components.</p> <p>Animal Study No animal testing was required or performed for the subject devices, as their design and materials do not necessitate such evaluation to establish safety and effectiveness.</p> <p>Clinical Studies No human clinical testing was required or performed for the subject devices, as their design and intended use do not necessitate such evaluation to establish safety and effectiveness.</p>				
<p>Comparison of Subject and Predicate Devices</p>	<p>The assessment of the comparison between the subject devices and the predicate device was based on a detailed device description, performance data, and conformance to consensus and voluntary standards.</p> <p>The testing included in this submission demonstrates that:</p> <ul style="list-style-type: none"> • Any differences in technological characteristics of the predicate device do not raise any new questions of safety or effectiveness. • The proposed devices are at least as safe and effective as the predicate device. 				
<p>Conclusion</p>	<p>The conclusions drawn from the non-clinical tests demonstrate that the subject devices in 510(k) submission K253791, the PUREVUE™ Quick Connect Cannula System Tray and PUREVUE™ Quick Connect Cannula System Lid, are as safe and effective as, and perform as well as or better than, the legally marketed predicate device cleared under K241927.</p>				