June 18, 2026

Mastel Surgical
Patrick Haney
Director, Mastel Surgical
1550 Samco Rd.
Rapid City, South Dakota 57702

Re: K253187
Trade/Device Name: SteriBest® Sterilization Tray System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: September 26, 2025
Received: September 26, 2025

Dear Patrick Haney:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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. ANISKO -S

Digitally signed by STEPHEN A. ANISKO -S
Date: 2026.06.18 15:45:25 -04'00'

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

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253187

Device Name
SteriBest® Sterilization Tray System

Indications for Use *(Describe)*

SteriBest® Sterilization Tray Systems are intended to organize, transport, store, and protect surgical and other medical devices during sterilization and between clinical uses. The trays are designed to allow sterilization of the enclosed medical devices during validated pre-vacuum steam sterilization cycles.

The SteriBest® Sterilization Tray Systems are not intended, on their own, to maintain sterility. The trays have perforations to permit sterilant penetration and must be used with a legally marketed, sterile barrier to maintain sterility until point of use.

Validated Sterilization Parameters:

Method	Pre-Vacuum Steam
Temperature	270 °F (132 °C)
Exposure Time	4 minutes
Dry Time	30 minutes

Maximum Load per Tray (Tray+ Instruments):

Tray Part Number	Maximum Load (g)
CP614	1794
CP634	1794
CP778	1794
CP471D1	366
CP471S	1794
CP1038D1	1049
CP1038D2	1794
CP1038S	1794

Validated Lumen Claims (Per Tray):
Validated lumens consisted of stainless steel.

Base and Lids (Tray) Part Number	count of lumens	ID of lumen (mm)	length of lumen (mm)
CP471D	4	1.0	152
CP1038D1	5	1.0	152
CP614	10	1.0	152
CP634	10	1.0	152
CP778	10	1.0	152
CP471S	10	1.0	152
CP1038D2	10	1.0	152
CP1038S	10	1.0	152

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.

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Department of Health and Human Services
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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510(k) Summary
K253187

I. Company: Mastel Surgical
II. Contact: Patrick Haney
Date: June 18, 2026

Device Name: SteriBest® Sterilization Tray System
Common Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Classification: 21 CFR 880.6850
Class: II
Product Code: KCT

III. Primary Predicate Devices: K171520, SteriZign Signatur Device Protection System

IV. Description:
The SteriBest® Sterilization Tray System is a reusable, perforated plastic tray system comprising tray bases, lids, mats, and bars designed to hold, organize, and protect reusable medical instruments and accessories during sterilization, transport, and storage. The trays feature a blue base, natural lid, and blue silicone inserts, with perforations to allow sterilant penetration and latching to secure the cover during handling. The mats and bars fit within the trays to allow for the organized arrangement of instruments, and all tray sizes have corresponding lids and bases. The system is available in 7 different tray sizes; the CP1038D2 is a multi-level tray comprising two tiers within a single tray assembly, while all other trays are single level. The trays, inserts, and accessories do not contact patients and do not independently maintain sterility.

Device List

Tray Part Number	Length (mm)	Width (mm)	Height (mm)
CP614	152	64	19
CP634	165	102	19
CP778	190.5	63.5	19
CP471D1	190.5	102	38
CP471S	190.5	102	19
CP1038D1	254	152	38
CP1038D2	254	152	38
CP1038S	254	152	19

List of Accessory Part Numbers:

Mats	Silicone Bars
CP614-7	CP2511P
CP634-7	CP2512P
CP778-7	CP2513P
CP471-7	CP4612P
CP1038-7	CP4613P
CP1038-3	CP4614P
	CP4615P

	CP2311P
	CP2312P
	CP2313P
	CP2314P

V. Indications for Use:

SteriBest® Sterilization Tray Systems are intended to organize, transport, store, and protect surgical and other medical devices during sterilization and between clinical uses. The trays are designed to allow sterilization of the enclosed medical devices during validated pre-vacuum steam sterilization cycles.

The SteriBest® Sterilization Tray Systems are not intended, on their own, to maintain sterility. The trays have perforations to permit sterilant penetration and must be used with a legally marketed, sterile barrier to maintain sterility until point of use.

Validated Sterilization Parameters:

Method	**Pre-Vacuum Steam**
Temperature	270 °F (132 °C)
Exposure Time	4 minutes
Dry Time	30 minutes

Maximum Load per Tray (Tray + Instruments):

Tray Part Number	Maximum Load (g)
CP614	1794
CP634	1794
CP778	1794
CP471D1	366
CP471S	1794
CP1038D1	1049
CP1038D2	1794
CP1038S	1794

Validated Lumen Claims (Per Tray):

Validated lumens consisted of stainless steel.

Base and Lids (Tray) Part Number	count of lumens	ID of lumen (mm)	length of lumen (mm)
CP471D	4	1.0	152
CP1038D1	5		
CP614	10		
CP634			
CP778			
CP471S			
CP1038D2			
CP1038S	10	1.0	152

VI Technological Characteristics Comparison Table

<table>
<tr><th></th><th>Subject Device</th><th>Primary Predicate Device</th><th>Comparison</th></tr>
<tr><td>Device Name</td><td>SteriBest® Sterilization Tray System</td><td>SteriZign Signatur Device Protection System</td><td></td></tr>
<tr><td>510(k) Number</td><td>K253187</td><td>K171520</td><td></td></tr>
<tr><td>Dimensions</td><td>
<table>
<tr><th>Tray Part Number</th><th>Length (mm)</th><th>Width (mm)</th><th>Height (mm)</th></tr>
<tr><td>CP614</td><td>152</td><td>64</td><td>19</td></tr>
<tr><td>CP634</td><td>165</td><td>102</td><td>19</td></tr>
<tr><td>CP778</td><td>190.5</td><td>63.5</td><td>19</td></tr>
<tr><td>CP471D1</td><td>190.5</td><td>102</td><td>38</td></tr>
<tr><td>CP471S</td><td>190.5</td><td>102</td><td>19</td></tr>
<tr><td>CP1038D1</td><td>254</td><td>152</td><td>38</td></tr>
<tr><td>CP1038D2</td><td>254</td><td>152</td><td>38</td></tr>
<tr><td>CP1038S</td><td>254</td><td>152</td><td>19</td></tr>
</table>
</td><td>Cat No. Size
102010-3 9.9"X20.5"</td><td>Similar</td></tr>
<tr><td>Indications for Use</td><td>SteriBest® Sterilization Tray Systems are intended to organize, transport, store, and protect surgical and other medical devices during sterilization and between clinical uses. The trays are designed to allow sterilization of the enclosed medical devices during validated pre-vacuum steam sterilization cycles.

The SteriBest® Sterilization Tray Systems are not intended, on their own, to maintain sterility. The trays have perforations to permit sterilant penetration and must be used with a legally marketed, sterile barrier to maintain sterility until point of use.

Validated Sterilization Parameters:
<table>
<tr><th>Method</th><th>Pre-Vacuum Steam</th></tr>
<tr><td></td><td></td></tr>
<tr><td>Exposure Time</td><td>4 minutes</td></tr>
<tr><td>Dry Time</td><td>30 minutes</td></tr>
</table>
Maximum Load per Tray (Tray + Instruments):
<table>
<tr><td>Tray Part Number</td><td>Maximum Load (g)</td></tr>
<tr><td>CP614</td><td>1794</td></tr>
<tr><td>CP634</td><td>1794</td></tr>
<tr><td>CP778</td><td>1794</td></tr>
<tr><td>CP471D1</td><td>366</td></tr>
<tr><td>CP471S</td><td>1794</td></tr>
<tr><td>CP1038D1</td><td>1049</td></tr>
<tr><td>CP1038D2</td><td>1794</td></tr>
<tr><td>CP1038S</td><td>1794</td></tr>
</table>
</td><td>SteriZign Signatur Device Cassette and Trays are used to organize, transport, store and protect between uses of surgical and other medical devices that are sterilized by a healthcare provider. SteriZign Signatur Device Cassette and Trays are intended to allow sterilization of the enclosed medical devices during a pre-vacuum steam sterilization cycles. The SteriZign Signatur Device Cassette and Trays are not intended on their own to maintain sterility. SteriZign Signatur Device Cassette and Trays have perforations and intended to be used in conjunction with legally marketed, validated FDA</td><td>Similar</td></tr>
</table>

<table>
<tr>
<td></td>
<td>
Validated Lumen Claims (Per Tray):
<table>
<tr><th>Base and Lids (Tray) Part Number</th><th>count of lumens</th><th>ID of lumen (mm)</th><th>length of lumen (mm)</th></tr>
<tr><td>CP471D</td><td>4</td><td rowspan="8">1.0</td><td rowspan="8">152</td></tr>
<tr><td>CP1038D1</td><td>5</td></tr>
<tr><td>CP614</td><td rowspan="6">10</td></tr>
<tr><td>CP634</td></tr>
<tr><td>CP778</td></tr>
<tr><td>CP471S</td></tr>
<tr><td>CP1038D2</td></tr>
<tr><td>CP1038S</td></tr>
</table>
</td>
<td>cleared sterilization wrap.

Autoclave Sterilization Parameter Cycle: Pre-vacuum
Temperature: 270°F (132°C)
Exposure Time: 4 minutes
Minimum Dry Time: 30 minutes</td>
<td></td>
</tr>
<tr>
<td>Lumen Claims</td>
<td>
<table>
<tr><th>Part Number</th><th>count of lumens</th><th>ID of lumen (mm)</th><th>length of lumen (mm)</th></tr>
<tr><td>CP614</td><td>10</td><td>1.0</td><td>152</td></tr>
<tr><td>CP634</td><td>10</td><td>1.0</td><td>152</td></tr>
<tr><td>CP778</td><td>10</td><td>1.0</td><td>152</td></tr>
<tr><td>CP471D</td><td>4</td><td>1.0</td><td>152</td></tr>
<tr><td>CP471S</td><td>10</td><td>1.0</td><td>152</td></tr>
<tr><td>CP1038D1</td><td>5</td><td>1.0</td><td>152</td></tr>
<tr><td>CP1038D2</td><td>10</td><td>1.0</td><td>152</td></tr>
<tr><td>CP1038S</td><td>10</td><td>1.0</td><td>152</td></tr>
</table>
</td>
<td>Lumen Inner Diameter (ID) x Length

1 mm 76 mm
1 mm 400 mm
2 mm 300 mm
3 mm 400 mm
5 mm 400 mm</td>
<td>Similar</td>
</tr>
<tr>
<td>Max Weights</td>
<td>The total weight of the container system (e.g. container, tray, and instrument load) must not the weights on the below chart.

Maximum Load per Tray (Tray + Instruments):
<table>
<tr><th>Tray Part Number</th><th>Maximum Load (g)</th></tr>
<tr><td>CP614</td><td>1794</td></tr>
<tr><td>CP634</td><td>1794</td></tr>
<tr><td>CP778</td><td>1794</td></tr>
<tr><td>CP471D1</td><td>366</td></tr>
<tr><td>CP471S</td><td>1794</td></tr>
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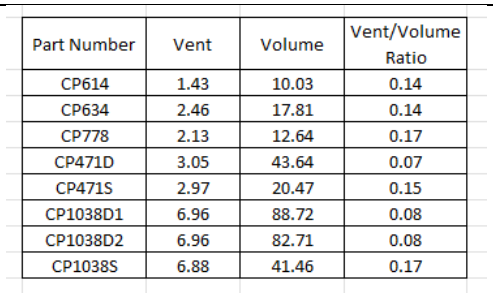
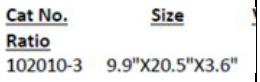
<tr><td>CP1038D2</td><td>1794</td></tr>
<tr><td>CP1038S</td><td>1794</td></tr>
</table>
</td>
<td>The total weight of the container system (e.g. container, tray, and instrument load) must not exceed 25 lbs.</td>
<td>Similar</td>
</tr>
<tr>
<td>Classification</td>
<td>880.6850</td>
<td>880.6850</td>
<td>Same</td>
</tr>
</table>

<table>
<tr><td>Regulation Name</td><td>Sterilization Wrap Containers, Trays, Cassettes & Other Accessories</td><td>Sterilization Wrap</td><td>Same</td></tr>
<tr><td>Class</td><td>2</td><td>2</td><td>Same</td></tr>
<tr><td>Product Code</td><td>KCT</td><td>KCT</td><td>Same</td></tr>
<tr><td>Description</td><td>The SteriBest® Sterilization Tray System is a reusable, perforated plastic tray system comprising tray bases, lids, mats, and bars designed to hold, organize, and protect reusable medical instruments and accessories during sterilization, transport, and storage. The trays feature a blue base, natural lid, and blue silicone inserts, with perforations to allow sterilant penetration and latching to secure the cover during handling. The mats and bars fit within the trays to allow for the organized arrangement of instruments, and all tray sizes have corresponding lids and bases. The system is available in 7 different tray sizes; the CP1038D2 is a multi-level tray comprising two tiers within a single tray assembly, while all other trays are single level. The trays, inserts, and accessories do not contact patients and do not independently maintain sterility.

Device List

<table>
<tr><th>Tray Part Number</th><th>Length (mm)</th><th>Width (mm)</th><th>Height (mm)</th></tr>
<tr><td>CP614</td><td>152</td><td>64</td><td>19</td></tr>
<tr><td>CP634</td><td>165</td><td>102</td><td>19</td></tr>
<tr><td>CP778</td><td>190.5</td><td>63.5</td><td>19</td></tr>
<tr><td>CP471D1</td><td>190.5</td><td>102</td><td>38</td></tr>
<tr><td>CP471S</td><td>190.5</td><td>102</td><td>19</td></tr>
<tr><td>CP1038D1</td><td>254</td><td>152</td><td>38</td></tr>
<tr><td>CP1038D2</td><td>254</td><td>152</td><td>38</td></tr>
<tr><td>CP1038S</td><td>254</td><td>152</td><td>19</td></tr>
</table>
List of Accessory Part Numbers:
<table>
<tr><td>Mats</td><td>Silicone Bars</td></tr>
<tr><td>CP614-7</td><td>CP2511P</td></tr>
<tr><td>CP634-7</td><td>CP2512P</td></tr>
<tr><td>CP778-7</td><td>CP2513P</td></tr>
<tr><td>CP471-7</td><td>CP4612P</td></tr>
<tr><td>CP1038-7</td><td>CP4613P</td></tr>
<tr><td>CP1038-3</td><td>CP4614P</td></tr>
<tr><td></td><td>CP4615P</td></tr>
<tr><td></td><td>CP2311P</td></tr>
<tr><td></td><td>CP2312P</td></tr>
<tr><td></td><td>CP2313P</td></tr>
<tr><td></td><td>CP2314P</td></tr>
</table></td><td>SteriZign Signatur Device Cassette and Trays are cassettes/trays used to enclose and hold surgical instruments and accessories in an organized manner during the sterilization process and subsequent storage and transportation. The cassettes/trays by themselves do not maintain sterility.

perforated base
perforated cover
silicone inserts (hold-it/ hold down)
silicone mat
brackets
handles</td><td>Similar</td></tr>
</table>

Material Composition	Trays and Lids: Ultem 1000 Mats: Silicone Silmix 61051 Bars: Silicone 10001930 EL R 401/70 S	Base: Aluminum Anodized Insert: Aluminum Anodized Lid: Aluminum Anodized Latch: 300 Series SS Passivated Handle: 300 Series SS Passivated Shelf Bracket: 300 Series SS Passivated Mat(s): Silicone Brackets: Polypropylene	Similar
Vent to Volume Calculation	 Part Number / Vent / Volume / Vent/Volume Ratio CP614 1.43 10.03 0.14 CP634 2.46 17.81 0.14 CP778 2.13 12.64 0.17 CP471D 3.05 43.64 0.07 CP471S 2.97 20.47 0.15 CP1038D1 6.96 88.72 0.08 CP1038D2 6.96 82.71 0.08 CP1038S 6.88 41.46 0.17	 Cat No. Size Ratio 102010-3 9.9"X20.5"X3.6"	Similar
Sterilization Parameters	Sterilant (steam) penetration through perforations in tray PreVacuum, 132 degrees C, 4-minute cycle, with 30 min dry time.	Sterilant (steam) penetration through perforations in tray PreVacuum, 132 degrees C, 4-minute cycle, with 30 min dry time.	Same
Microbial Barrier Properties	The SteriBest® Sterilization Tray System is intended to be used in conjunction with a legally marketed sterile barrier. The SteriBest® Sterilization Tray System is not intended on their own to maintain sterility.	SteriZign Signatur Device Cassette and Trays is intended to be used in conjunction with a legally marketed wrap. The SteriZign Signature Device	Same

		Cassette and Trays are not intended on their own to maintain sterility.	
Air Permeance	Yes	Yes	Same
Material Compatibility	Materials of construction are compatible with steam sterilization	Materials of construction are compatible with steam sterilization	Same
Technological Properties (Biocompatibility)	MEM Elution Cytotoxicity (ISO 10993-5). The test samples meet the USP and ISO 10993-5 requirements for this test. All controls were acceptable and the test was considered valid. The test samples passed and are considered non-cytotoxic under the test conditions employed.	MEM Elution Cytotoxicity (ISO 10993-5). The test samples meet the USP and ISO 10993-5 requirements for this test. All controls were acceptable and the test was considered valid. The test samples passed and are considered non-cytotoxic under the test conditions employed.	Same
Aeration Time	NA	NA	Same
Technical Characteristics	The technological characteristics of the subject devices are similar to the predicate devices. The trays and component accessories are made of standard medical grade materials and do not incorporate any new technological characteristics.	The technological characteristics of the subject devices are similar to the predicate devices. The cassettes/trays are made of standard medical grade materials and do not incorporate any new technological characteristics.	Same
Sterilant Penetration	The purpose of this study was to verify that the SteriBest® Sterilization Tray System allows for sufficient sterilant penetration when exposed to a pre-vacuum steam 132 deg C two (2) minute sterilization half cycle. The requirements for sterilization, drying, and post-sterilization biocompatibility of materials were evaluated as described in ANSI/AAMI ST77:2013: Containment devices for reusable medical device sterilization.	The purpose of this study was to verify that the SteriZign Signatur Device Cassette and Trays allows for sufficient sterilant penetration when exposed to a pre-vacuum steam	Same

		132 deg C two (2) minute sterilization half cycle. The requirements for sterilization, drying, and post-sterilization biocompatibility of materials were evaluated as described in ANSI/AAMI ST77:2013: Containment devices for reusable medical device sterilization.	
Shelf Life	The trays may be reused until signs of deterioration are observed, including cracks, deformation/warping, broken latches, missing or damaged silicone inserts, or discoloration. Replace immediately if any of these conditions are present. No fixed maximum number of reprocessing cycles is specified; trays are suitable for repeated use under the cleaning/sterilization conditions provided.	The life of the System is limited only by irreparable physical damage from mishandling. Always inspect the system before use for wear and damage and discontinue use if visible signs of damage are visible; i.e. flaking, cracks, fading, sharp edges. Always inspect the system between uses and repair or replace tray components as necessary.	Same
Drying Time	30 mins	30 mins	Same

VII. Non-Clinical Testing

Test/Standard	Acceptance Criteria	Results
Steam Sterilization Efficacy The sterilization process was validated using the overkill method as described in ISO 17665-2.	A confirmed BI population of approximately 10^6 CFU Negative tests for G. stearothermophilus on all inoculated samples from each half cycle per cycle parameter. Positive test(s) for *G. stearothermophilus* on all associated positive control	The subject devices passed the acceptance criteria and met the requirements. The study results provide evidence that the SteriBest® Sterilization Tray System can be steam sterilized to a sterility assurance level (SAL) of at least 10^{-6} using the full cycle parameters show in the below table.

	samples. Autoclave data showing dwell time and temperatures (+ 3 °C) for all the half cycles are met. In the event results do not meet the acceptance criteria, the client will be notified, and a path forward will be discussed with the potential of a protocol deviation describing a revised method of testing.	<table><tr><th></th><th colspan="2">Cycle Parameters</th></tr><tr><th>Cycle Type</th><th>Sterilization Temperature</th><th>Sterilization Exposure Time</th></tr><tr><td>Pre-vacuum</td><td>132 °C</td><td>4 minutes</td></tr></table>
Dry Time Validation The drying time was validated through evaluation of moisture present on the product and packaging upon completion of the full sterilization processing cycle.	Autoclave data showing the dwell time and temperatures (+ 3 °C) and the specified dry time for each full cycle are met The confirmation of the absence of visible moisture from the instrument tray and its respective packaging for each cycle. No more than a 3% increase in weight from prior to sterilization and after sterilization of the instrument tray for each cycle. No more than a 3% increase in weight from prior to sterilization and after sterilization of the packaging for each cycle.	The subject devices passed the acceptance criteria and met the requirements. The study results demonstrate that the SteriBest Sterilization Tray System can be effectively dried following sterilization. Post-sterilization weight measurements showed that the combined tray and packaging system exhibited a weight increase of no more than 3% compared to pre-sterilization baseline weights, meeting the predefined acceptance criteria for residual moisture.
Biocompatibility MEM Elution Cytotoxicity Assay (ISO) This study was based on the requirements of the International Organization for Standardization (ISO) 10993-5, Biological evaluation of	Each of the triplicate test article and control wells must produce similar responses (± 1 grade). The vehicle control must receive a grade of zero in triplicate. The negative control must receive a grade of zero in triplicate.	The subject devices passed the acceptance criteria and met the requirements. No cytotoxicity or cell lysis was noted in any of the test wells. The vehicle control, negative control and the positive control performed as anticipated. 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 or equal to a grade 2 (mild reactivity).

medical devices - Part 5: Tests for *in vitro* cytotoxicity. Study articles were prepared based on International Organization for Standardization 10993-12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.	The positive control must produce a cytotoxic response in triplicate.	
Manual Cleaning Validation Protein Analysis AAMI/ANSI ST98: 2022	Each test sample shall show a protein level of less than 6.4 µg/cm2 after cleaning. Each test sample shall show no visible soil after cleaning. The extraction efficiency shall be greater than or equal to 70%. 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.	The subject devices passed the acceptance criteria and met the requirements. Each test sample showed a protein level of less than 6.4 µg/cm2 after cleaning. Each test sample showed no visible soil after cleaning. The extraction efficiency was greater than 70%. The standard deviation of the sample set added to the concentration of the highest data point did not exceed the acceptance criterion of 6.4 µg/cm2.
Manual Cleaning Validation Hemoglobin Analysis AAMI/ANSI ST98: 2022	Each test sample shall show a hemoglobin level of less than 2.2 µg/cm2 after cleaning. Each test sample shall show no visible soil after cleaning. The extraction efficiency shall be greater than or equal to 70%. The standard deviation of the sample set added to the concentration of the highest data point shall not exceed the acceptance criterion of 2.2 µg/cm2.	The subject devices passed the acceptance criteria and met the requirements. Each test sample showed a hemoglobin level of less than 2.2 µg/cm2 after cleaning. Each test sample showed no visible soil after cleaning. The extraction efficiency was greater than 70%. The standard deviation of the sample set added to the concentration of the highest data point did not exceed the acceptance criterion of 2.2 µg/cm2.

VIII. Clinical Testing

N/A – Not applicable for this submission.

IX. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, SteriBest® Sterilization Tray System, is a safe, as effective, and performs as well as or better than the legally marketed predicate SteriZign Signatur Device Protection System (K171520).