February 18, 2021

BEGO Implant Systems GmbH & Co. KG
Bertrand Lecointe
Regulatory Affairs Manager
Wilhelm-Herbst-Str. 1
Bremen, 28359 De

Re: K201412
Trade/Device Name: BEGO SEMADOS Tr 58350, BEGO Semados Tr 58349, BEGO Semados DSTr 58356, BEGO SEMADOS PKTr 58357
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: January 19, 2021
Received: January 25, 2021

Dear Bertrand Lecointe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to 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,

Clarence Murray III, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K201412

Device Name

BEGO SEMADOS® Tr 58350, BEGO Semados® Tr 58349, BEGO Semados® DSTr 58356, BEGO SEMADOS® PKTr 58357

Indications for Use *(Describe)*

BEGO SEMADOS® Tr 58350, BEGO Semados® Tr 58349, BEGO Semados® DSTr 58356, BEGO SEMADOS® PKTr 58357 are intended to store and organize the BEGO Semados® surgical instruments, insertion tools, drill stops and prosthetic instruments during both steam sterilization in an autoclave and implant/ prosthetic treatments.

BEGO SEMADOS® Tr 58350, BEGO Semados® Tr 58349, BEGO Semados® DSTr 58356, BEGO SEMADOS® PKTr 58357 are not intended on its own to maintain sterility; it is intended to be used with a legally marketed, validated, FDA-cleared sterilization pouch.

Cycle	Temperature	Exposure Time	Drying Time
Fractioned pre-vacuum steam	132°C (270°F)	4 min	20 min

Sterilization validations included the worst-case load configurations and has the maximum load including instruments for the following device models:

Device Model	Maximum load (wt), including instruments	Type of Instruments
BEGO SEMADOS® Tr 58350	476 g	Surgical instruments, insertion tools
BEGO Semados® Tr 58349	261 g	Surgical instruments, insertion tools
BEGO Semados® DSTr 58356	137 g	Drill stops
BEGO SEMADOS® PKTr 58357	220 g	Insertion tools, prosthetic instruments

Healthcare facilities should not exceed 25 pounds (BEGO Semados® Trays containment device + sterile pouch + surgical instruments/insertion tools/drill stop/prosthetic instruments).

Sterilization validations included the worst-case load configurations of following lumen sizes and dimensions and has the maximum load for the following device models:

Device Model	Type of Lumen	Number of lumens	Sizes & Dimensions [mm]
BEGO SEMADOS® Tr 58350	Drill holes	8	Ø1.2, L2.4 / Ø 1.2, L 6.8 / Ø 2.4-2.9, L 22.5/14.6 / Ø1.2, L6.8
	Oval hole	1	2.3 x 2.0
BEGO Semados® Tr 58349	Drill holes	4	Ø1.2, L2.4 / Ø2.4, L16
	Oval hole	1	2.3x2.0
BEGO Semados® DSTr 58356	Drill holes	25	Ø 2.6-5.1, L 6-12
BEGO SEMADOS® PKTr 58357	Drill holes	5	Ø 2.4, L16 / Ø 1.2, L 6.8

BEGO SEMADOS® Tr 58350, BEGO Semados® Tr 58349, BEGO Semados® DSTr 58356, BEGO SEMADOS® PKTr 58357 are offered in the following sizes:

Device Model	Dimensions [mm]
BEGO SEMADOS® Tr 58350	188.1 x 138.7 x 61.5
BEGO Semados® Tr 58349	142.7 x 99.6 x 61
BEGO Semados® DSTr 58356	80 x 85 x 28
BEGO SEMADOS® PKTr 58357	140 x 80 x 25

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K201412

Submitter Information: BEGO Implant Systems GmbH & Co. KG
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BEGO Implant Systems GmbH & Co. KG
Phone: +49 (0) 421 2028-230
E-Mail: IM-RA@bego.com

Date Prepared: 2/17/2021

510(k) No.: **K201412**

Name of Device: BEGO SEMADOS® Tr 58350, BEGO Semados® Tr 58349, BEGO Semados® DSTr 58356, BEGO SEMADOS® PKTr 58357

Common name: BEGO Semados® Trays

Classification Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories

Product Code: KCT

C.F.R. Section: 21 CFR 880.6850

Classification Panel: General Hospital

Regulation Class: Class II

Predicate Device Information

Primary Predicate

Device Trade Name:	Straumann BLX Surgical Cassette
Applicant:	Institut Straumann AG
510(k) No.:	K180791

Reference Device

Device Trade Name:	PureSet Tray
Applicant:	Nobel Biocare AB
510(k) No.:	K181075

Device(s) Identification

Subject of this submission are the BEGO Semados® Trays (58350, 58349, 58356, 58357) that are parts of BEGO Semados® implant/ prosthetic treatment sets/ kits. The below table specifies the devices that are subject of this submission. The empty trays are highlighted in bold in all tables of this submission for identification purposes.

Overview BEGO Semados® Trays

	Trade or Proprietary or Model Name for This Device	Model number	Product Code
1	**BEGO SEMADOS® Tr 58350**	**58350**	**KCT**
	BEGO SEMADOS® RS/RSX-LINE TRAY PLUS	57949	Kit containing device KCT
2	**BEGO Semados® Tr 58349**	**58349**	**KCT**
	BEGO Semados® Tr 58348	58348	Kit containing device KCT
3	**BEGO Semados® DSTr 58356**	**58356**	**KCT**
	DRILL STOP TRAY PLUS (RS/RSX-LINE)	57483	Kit containing device KCT
4	**BEGO SEMADOS® PKTr 58357**	**58357**	**KCT**
	PROSTHETIC KIT	55826	Kit containing device KCT

Note: The instruments and accessory devices that are intended to be sterilized and stored in the subject Trays, are not subject to this submission.

Indications for use

BEGO SEMADOS® Tr 58350, BEGO Semados® Tr 58349, BEGO Semados® DSTr 58356, BEGO SEMADOS® PKTr 58357 are intended to store and organize the BEGO Semados® surgical instruments, insertion tools, drill stops and prosthetic instruments during both steam sterilization in an autoclave and implant/ prosthetic treatments.

BEGO SEMADOS® Tr 58350, BEGO Semados® Tr 58349, BEGO Semados® DSTr 58356, BEGO SEMADOS® PKTr 58357 are not intended on its own to maintain sterility; it is intended to be used with a legally marketed, validated, FDA-cleared sterilization pouch.

Cycle	Temperature	Exposure Time	Drying Time
Fractioned pre-vacuum steam	132°C (270°F)	4 min	20 min

Sterilization validations included the worst-case load configurations and has the maximum load including instruments for the following device models:

Device Model	Maximum load (wt), including instruments	Type of Instruments
BEGO SEMADOS® Tr 58350	476 g	Surgical instruments, insertion tools
BEGO Semados® Tr 58349	261 g	Surgical instruments, insertion tools
BEGO Semados® DSTr 58356	137 g	Drill stops
BEGO SEMADOS® PKTr 58357	220 g	Insertion tools, prosthetic instruments

Healthcare facilities should not exceed 25 pounds (BEGO Semados® Trays containment device + sterile pouch + surgical instruments/insertion tools/drill stop/prosthetic instruments).

Sterilization validations included the worst-case load configurations of following lumen sizes and dimensions and has the maximum load for the following device models:

Device Model	Type of Lumen	Number of lumens	Sizes & Dimensions [mm]
BEGO SEMADOS® Tr 58350	Drill holes	8	Ø1.2, L2.4 / Ø 1.2, L 6.8 / Ø 2.4-2.9, L 22.5/14.6 / Ø1.2, L6.8
	Oval hole	1	2.3 x 2.0
BEGO Semados® Tr 58349	Drill holes	4	Ø1.2, L2.4 / Ø2.4, L16
	Oval hole	1	2.3x2.0
BEGO Semados® DSTr 58356	Drill holes	25	Ø 2.6-5.1, L 6-12
BEGO SEMADOS® PKTr 58357	Drill holes	5	Ø 2.4, L16 / Ø 1.2, L 6.8

BEGO SEMADOS® Tr 58350, BEGO Semados® Tr 58349, BEGO Semados® DSTr 58356, BEGO SEMADOS® PKTr 58357 are offered in the following sizes:

Device Model	Dimensions [mm]
BEGO SEMADOS® Tr 58350	188.1 x 138.7 x 61.5
BEGO Semados® Tr 58349	142.7 x 99.6 x 61
BEGO Semados® DSTr 58356	80 x 85 x 28
BEGO SEMADOS® PKTr 58357	140 x 80 x 25

Device Description

BEGO SEMADOS® Tr 58350

BEGO SEMADOS® Tr 58350 is composed of three main components: a tray cover, a tray container and a tray insert, all made of polyphenylsulfone. The tray container and the tray insert have additional silicone rubber grommets to store and organize the BEGO Semados® surgical instruments and insertion tools. The tray container and tray insert are printed to indicate the surgical workflow and the position of the above mentioned instruments within the tray for reprocessing and implant/ prosthetic treatments.

BEGO SEMADOS® Tr 58350 is supplied without BEGO Semados® surgical instruments and insertion tools.

BEGO SEMADOS® RS/RSX-LINE TRAY PLUS is supplied as a kit with BEGO SEMADOS® Tr 58350 and BEGO Semados® surgical instruments and insertion tools.

BEGO Semados® Tr 58349

BEGO Semados® Tr 58349 is composed of three main components: a tray cover, a tray container and a tray insert, all made of polyphenylsulfone. The tray container and the tray insert have additional silicone rubber grommets to store and organize the BEGO Semados® surgical instruments and insertion tools. The tray container and tray insert are printed to indicate the surgical workflow and the position of the above mentioned instruments within the tray for reprocessing and implant/ prosthetic treatments.

BEGO Semados® Tr 58349 is supplied without BEGO Semados® surgical instruments and insertion tools.

BEGO Semados® Tr 58348 is supplied as a kit with BEGO Semados® Tr 58349 and BEGO Semados® surgical instruments and insertion tools.

BEGO Semados® DSTr 58356

BEGO Semados® DSTr 58356 is composed of two main components: a tray cover made of polyphenylsulfone and a tray container made of polypropylene. The tray container has inserts to store and organize the drill stops. The tray container is printed to indicate the position of the drill stops within the tray for reprocessing and implant treatments.

BEGO Semados® DSTr 58356 is supplied without drill stops.

DRILL STOP TRAY PLUS (RS/RSX-Line) is supplied as a kit with BEGO Semados® DSTr 58356 and drill stops.

BEGO SEMADOS® PKTr 58357

BEGO SEMADOS® PKTr 58357 is composed of two main components: a tray cover made of polyphenylsulfone and a tray container made of polypropylene. The tray container has inserts to store

and organize the BEGO Semados® insertion tools and prosthetic instruments. The tray container is printed to indicate the position of the above mentioned instruments within the tray for reprocessing and implant/prosthetic treatments.

BEGO SEMADOS® PKTr 58357 is supplied without BEGO Semados® insertion tools and prosthetic instruments.

PROSTHETIC KIT is supplied as a kit with BEGO SEMADOS® PKTr 58357 and BEGO Semados® insertion tools and prosthetic instruments.

Intended Use:

BEGO Semados® Trays are intended to store and organize the BEGO Semados® medical devices during both steam sterilization in an autoclave and implant/ prosthetic treatments.

BEGO Semados® Trays are not intended on their own to maintain sterility; they are intended to be used with a legally marketed, validated, FDA-cleared sterilization pouch.

Summary of technological characteristics

The below table presents the comparison of functions and parameters of the identified Predicate Device and the BEGO Semados® Trays.

Comparison between Subject and Predicate Device

<table>
<tr><th></th><th>Subject Device</th><th>Predicate Device</th><th></th></tr>
<tr><th>Feature</th><th>BEGO Semados® Trays (K201412)</th><th>Straumann BLX Surgical Cassette (K180791)</th><th>Comparison</th></tr>
<tr><td>Indications for Use</td><td>BEGO SEMADOS® Tr 58350, BEGO Semados® Tr 58349, BEGO Semados® DSTr 58356, BEGO SEMADOS® PKTr 58357 are intended to store and organize the BEGO Semados® surgical instruments, insertion tools, drill stops and prosthetic instruments during both steam sterilization in an autoclave and implant/ prosthetic treatments.

BEGO SEMADOS® Tr 58350, BEGO Semados® Tr 58349, BEGO Semados® DSTr 58356, BEGO SEMADOS® PKTr 58357 are not intended on its own to maintain sterility; it is intended to be used with a legally marketed, validated, FDA-cleared sterilization pouch.
<table>
<tr><th>Cycle</th><th>Temperature</th><th>Exposure Time</th><th>Drying Time</th></tr>
<tr><td>Fractioned pre-vacuum steam</td><td>132°C (270°F)</td><td>4 min</td><td>20 min</td></tr>
</table>
Sterilization validations included the worst-case load configurations and has the maximum load including instruments for the following device models:
<table>
<tr><th>Device Model</th><th>Maximum load (wt), including instruments</th><th>Type of Instruments</th></tr>
<tr><td>BEGO SEMADOS® Tr 58350</td><td>476 g</td><td>Surgical instruments, insertion tools</td></tr>
<tr><td>BEGO Semados® Tr 58349</td><td>261 g</td><td>Surgical instruments, insertion tools</td></tr>
<tr><td>BEGO Semados® DSTr 58356</td><td>137 g</td><td>Drill stops</td></tr>
</table></td><td>The Straumann BLX Cassette is used in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices between surgical uses. The BLX Cassette is not intended to maintain sterility; it is intended to conjunction with a legally marketed, validated sterilization wrap.
The BLX Cassette has been validated for a maximum load of 300 grams, including cassette and instruments.
Sterilization parameters: Pre-vacuum steam: 132°C (270°F) for 4 minutes with 20 minutes drying time.</td><td>Similar</td></tr>
</table>

	Subject Device	Predicate Device	
Feature	**BEGO Semados® Trays (K201412)**	**Straumann BLX Surgical Cassette (K180791)**	**Comparison**

BEGO SEMADOS® PKTr 58357	220 g	Insertion tools, prosthetic instruments

Healthcare facilities should not exceed 25 pounds (BEGO Semados® Trays containment device + sterile pouch + surgical instruments/insertion tools/drill stop/prosthetic instruments).

Sterilization validations included the worst-case load configurations of following lumen sizes and dimensions and has the maximum load for the following device models:

Device Model	**Type of Lumen**	**Number of lumen**	**Sizes & Dimensions [mm]**
BEGO SEMADOS® Tr 58350	Drill holes	8	Ø1.2, L2.4 / Ø 1.2, L 6.8 / Ø 2.4-2.9, L 22.5/14.6 / Ø1.2, L6.8
	Oval hole	1	2.3 x 2.0
BEGO Semados® Tr 58349	Drill holes	4	Ø1.2, L2.4 / Ø2.4, L16
	Oval hole	1	2.3x2.0
BEGO Semados® DSTr 58356	Drill holes	25	Ø 2.6-5.1, L 6-12
BEGO SEMADOS® PKTr 58357	Drill holes	5	Ø 2.4, L16 / Ø 1.2, L 6.8

BEGO SEMADOS® Tr 58350, BEGO Semados® Tr 58349, BEGO Semados® DSTr 58356, BEGO SEMADOS® PKTr 58357 are offered in the following sizes:

Device Model	**Dimensions [mm]**
BEGO SEMADOS® Tr 58350	188.1 x 138.7 x 61.5
BEGO Semados® Tr 58349	142.7 x 99.6 x 61
BEGO Semados® DSTr 58356	80 x 85 x 28
BEGO SEMADOS® PKTr 58357	140 x 80 x 25

<table>
<tr><td></td><td>Subject Device</td><td>Predicate Device</td><td></td></tr>
<tr><td>Feature</td><td>BEGO Semados® Trays (K201412)</td><td>Straumann BLX Surgical Cassette (K180791)</td><td>Comparison</td></tr>
<tr><td>Intended Use</td><td>BEGO Semados® Trays are intended to store and organize the BEGO Semados® medical devices during both steam sterilization in an autoclave and implant/ prosthetic treatments.
BEGO Semados® Trays are not intended on their own to maintain sterility; they are intended to be used with a legally marketed, validated, FDA-cleared sterilization pouch.</td><td>The Straumann BLX Cassette is used in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices between surgical uses. The BLX Cassette is not intended to maintain sterility; it is intended to conjunction with a legally marketed, validated sterilization wrap.</td><td>Identical</td></tr>
<tr><td>Product Code</td><td>KCT</td><td>KCT</td><td>Identical</td></tr>
<tr><td>Reusable</td><td>Yes</td><td>Yes</td><td>Identical</td></tr>
<tr><td>Sterilization Method</td><td>Moist Heat (Steam)</td><td>Moist Heat (Steam)</td><td>Identical</td></tr>
<tr><td>Cycle</td><td>Dynamic-Air-Removal (fractionated vacuum)</td><td>Pre-vacuum</td><td>Identical</td></tr>
<tr><td>Temperature</td><td>132°C (270°F)</td><td>132°C (270°F)</td><td>Identical</td></tr>
<tr><td>Exposure time</td><td>4 minutes</td><td>4 minutes</td><td>Identical</td></tr>
<tr><td>Drying time</td><td>20-30 minutes</td><td>20 minutes</td><td>Similar</td></tr>
<tr><td>Sterile Barrier</td><td>FDA-cleared sterilization pouch</td><td>FDA-cleared sterilization wrap</td><td>Different</td></tr>
<tr><td>Maximum Load</td><td><table><tr><th>Device Model</th><th>Maximum load (wt), including instruments</th></tr><tr><td>BEGO SEMADOS® Tr 58350</td><td>476 g</td></tr><tr><td>BEGO Semados® Tr 58349</td><td>261 g</td></tr><tr><td>BEGO Semados® DSTr 58356</td><td>137 g</td></tr><tr><td>BEGO SEMADOS® PKTr 58357</td><td>220 g</td></tr></table></td><td>300g, including cassette and instruments</td><td>Different</td></tr>
<tr><td>Vent to volume ratio</td><td><table><tr><th>Device Model</th><th>V-to-V ratio</th></tr><tr><td>BEGO SEMADOS® Tr 58350</td><td>0.084 in^2/in^3</td></tr></table></td><td>0.054 in^2/in^3</td><td>Different</td></tr>
</table>

	Subject Device	Predicate Device	
Feature	**BEGO Semados® Trays (K201412)**	**Straumann BLX Surgical Cassette (K180791)**	**Comparison**
	BEGO Semados® Tr 58349: 0.072 in^2/in^3 BEGO Semados® DSTr 58356: 0.601 in^2/in^3 BEGO SEMADOS® PKTr 58357: 0.241 in^2/in^3		
Device Construction	BEGO SEMADOS® Tr 58350/ BEGO Semados® Tr 58349: Plastic tray, lid and insert BEGO Semados® DSTr 58356/ BEGO SEMADOS® PKTr 58357: Plastic tray and lid	Plastic tray and lid	Similar
Perforated	Yes, allows moist heat (steam) penetration to achieve sterilization	Yes, allows moist heat (steam) penetration to achieve sterilization	Identical
Material Composition	BEGO SEMADOS® Tr 58350/ BEGO Semados® Tr 58349: - Polyphenylsulfone (PPSU Radel® R5000) - Silicone/ Polydimethylsiloxane BEGO Semados® DSTr 58356/ BEGO SEMADOS® PKTr 58357: - Polyphenylsulfone (PPSU Radel® R5000 - Polypropylene Heat Stabilized (PP-HS)	Polyphenylsulfone (Radel® R5000) Silicone	Similar
Material compatibility with sterilization process	Yes	Yes	Identical
Enclosing feature	BEGO SEMADOS® Tr 58350/ BEGO Semados® Tr 58349: Silicone rubber grommets	Silicone grommets	Similar

<table>
<tr><td></td><td>Subject Device</td><td>Predicate Device</td><td></td></tr>
<tr><td>Feature</td><td>BEGO Semados® Trays (K201412)</td><td>Straumann BLX Surgical Cassette (K180791)</td><td>Comparison</td></tr>
<tr><td></td><td>BEGO Semados® DSTr 58356/ BEGO SEMADOS® PKTr 58357: None</td><td></td><td></td></tr>
<tr><td>Dimension</td><td><table><tr><td>Device Model</td><td>Dimension [mm]</td></tr><tr><td>BEGO SEMADOS® Tr 58350</td><td>188.1 x 138.7 x 61.5</td></tr><tr><td>BEGO Semados® Tr 58349</td><td>142.7 x 99.6 x 61</td></tr><tr><td>BEGO Semados® DSTr 58356</td><td>80 x 85 x 28</td></tr><tr><td>BEGO SEMADOS® PKTr 58357</td><td>140 x 80 x 25</td></tr></table></td><td>143 mm x 100 mm x 61 mm</td><td>Different</td></tr>
</table>

Summary of non-clinical testing

Provided below is a summary table of the non-clinical testing that were performed using the subject device. The result demonstrated that the subject device non-clinical test results met the acceptance criteria of the standards.

Non-Clinical Performance Testing Table

Test/ Methodology	Purpose	Acceptance Criteria	Results
AAMI TIR30:2011	Automated Cleaning Validation – Protein Analysis	Verify cleaning instructions provided are efficacious for removing gross amounts of soil to a residual protein level of 6.4 µg protein/cm^2	The automated cleaning validation of BEGO Semados® Trays concluded that the manufacturer's cleaning instructions are efficacious for removing gross amounts of soil to a residual protein level of 6.4 µg protein/cm^2.
AAMI TIR30:2011	Automated Cleaning Validation – Organic Carbon Analysis	Verify cleaning instructions provided are efficacious for removing gross amounts of soil to a total organic carbon (TOC) content of 3.1 µg of C/cm^2	The automated cleaning validation of BEGO Semados® Trays concluded that the manufacturer's cleaning instructions are efficacious for removing gross amounts of soil to a total organic carbon (TOC) content of 3.1 µg of C/cm^2.
ISO 10993-5:2009	Cell Growth Analysis via XTT-Staining	Verify the device does not have a cytotoxic potential. An inhibition of cell growth (ICG) of more than 30% is considered as cytotoxic effect.	The cytotoxicity testing concluded that test devices met the requirements of the test and are not considered to have a cytotoxic potential.
ISO 17665-1:2006-08 ISO TS 17665-2:2009-01 ANSI/AAMI ST77:2013	Sterilization validation	Verify the device and cycle parameters achieve a Sterility Assurance Level (SAL) of 10^{-6}.	The tested devices achieved a SAL of 10-6 after processing in pre-vacuum steam sterilization cycle at 132°C for 4 minutes.
AAMI TIR12:2010	Drying Time testing	Verify the device is properly dried using the specified cycle parameters.	The BEGO Semados® Trays are considered properly dried following processing in pre-vacuum steam sterilization cycle at 132°C for 4 minutes, and drying time of 20 minutes.

Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the BEGO SEMADOS® Tr 58350, BEGO Semados® Tr 58349, BEGO Semados® DSTr 58356, BEGO SEMADOS® PKTr 58357 Device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Straumann BLX Surgical Cassette.