December 18, 2024

Soadco, S.L.
% Rebecca Kattan
Regulatory Specialist
PaxMed International, LLC
12264 El Camino Real
Suite 400
San Diego, California 92130

Re: K243128
Trade/Device Name: Klockner Kits
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: September 29, 2024
Received: September 30, 2024

Dear Rebecca Kattan:

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

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2024.12.18 17:36:15 -05'00'

for: Christopher K. Dugard
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K243128

Device Name
KLOCKNER KITS

Indications for Use *(Describe)*

Indications for Use for the KIT WT SNIPER
KLOCKNER KITS are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. KLOCKER KITS are intended to allow sterilization of the enclosed medical devices.
KLOCKNER KITS require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.
The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Dynamic air removal steam sterilization – Exposure at 134 °C for 4 minutes and 16 minutes dry time.
KLOCKNER KITS are intended for sterilization of non-porous loads.
KLOCKNER KITS are recommended not to be stacked during sterilization.
The combined weight of the KIT WT SNIPER and the associated instruments is 820 grams.
The weight of the empty KIT WT SNIPER is 620 grams.

The KIT WT SNIPER is exclusively indicated to assist in the installation of implants of the VEGA® and ESSENTIAL® CONE 1.5 families and is not compatible with other lines and systems of other manufacturers.

Indications for Use for the KIT WT SNIPER JSI
KLOCKNER KITS are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. KLOCKNER KITS are intended to allow sterilization of the enclosed medical devices.
KLOCKNER KITS require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.
The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Dynamic air removal steam sterilization – Exposure at 134 °C for 4 minutes and 16 minutes dry time.
KLOCKNER KITS are intended for sterilization of non-porous loads.
KLOCKNER KITS are recommended not to be stacked during sterilization.
The combined weight of the KIT WT SNIPER JSI and the associated instruments is 920 grams.
The weight of the empty KIT WT SNIPER JSI is 620 grams.

The KIT WT SNIPER JSI is exclusively indicated to assist in the installation of implants of the VEGA® and ESSENTIAL® CONE 1.5 families and is not compatible with other lines and systems of other manufacturers.

Indications for Use for the KIT WT INTERNA
KLOCKNER KITS are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. KLOCKNER KITS are intended to allow sterilization of the enclosed medical devices.
KLOCKNER KITS require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.
The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Dynamic air removal steam sterilization – Exposure at 134 °C for 4 minutes and 16 minutes dry time.
KLOCKNER KITS are intended for sterilization of non-porous loads.
KLOCKNER KITS are recommended not to be stacked during sterilization.
The combined weight of the KIT WT INTERNA and the associated instruments is 840 grams.

The KIT WT INTERNA is exclusively indicated to assist in the installation of implants of both the VEGA® and ESSENTIAL® CONE families and is not compatible with other lines and systems of other manufacturers.

Indications for Use for the KIT WT VEGA
KLOCKNER KITS are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. KLOCKNER KITS are intended to allow sterilization of the enclosed medical devices.
KLOCKNER KITS require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.
The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Dynamic air removal steam sterilization – Exposure at 134 °C for 4 minutes and 16 minutes dry time.
KLOCKNER KITS are intended for sterilization of non-porous loads.
KLOCKNER KITS are recommended not to be stacked during sterilization.
The combined weight of the KIT WT VEGA and the associated instruments is 820 grams.
The weight of the empty KIT WT VEGA is 620 grams.

The KIT WT VEGA is exclusively indicated to assist in the installation of implants of the VEGA® family and is not compatible with other lines and systems of other manufacturers.

Indications for Use for the KIT WT ESSENTIAL
KLOCKNER KITS are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. KLOCKNER KITS are intended to allow sterilization of the enclosed medical devices.
KLOCKNER KITS require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.
The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Dynamic air removal steam sterilization – Exposure at 134 °C for 4 minutes and 16 minutes dry time.
KLOCKNER KITS are intended for sterilization of non-porous loads.
KLOCKNER KITS are recommended not to be stacked during sterilization.
The combined weight of the KIT WT ESSENTIAL and the associated instruments is 800 grams.
The weight of the empty KIT WT ESSENTIAL is 620 grams.

The KIT WT ESSENTIAL is exclusively indicated to assist in the installation of implants of the ESSENTIAL® CONE family and is not compatible with other lines and systems of other manufacturers.

Indications for Use for the KIT MEDGUIDE®
KLOCKNER KITS are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. KLOCKNER KITS are intended to allow sterilization of the enclosed medical devices.
KLOCKNER KITS require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.
The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Dynamic air removal steam sterilization – Exposure at 134 °C for 4 minutes and 16 minutes dry time.
KLOCKNER KITS are intended for sterilization of non-porous loads.
KLOCKNER KITS are recommended not to be stacked during sterilization.
The combined weight of the KIT MEDGUIDE® and the associated instruments is 240 grams.
The weight of the empty KIT MEDGUIDE® is 160 grams.

The KIT MEDGUIDE® is exclusively indicated to assist in the installation of implants of the VEGA® and ESSENTIAL® CONE families and is not compatible with other lines and systems of other manufacturers.

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
K243128
SOADCO, S.L.
KLOCKNER KITS

December 12, 2024

ADMINISTRATIVE INFORMATION

Manufacturer Name	SOADCO, S.L. Av. Pessebre, 76-82, Baixos AD700 Escaldes-Engordany, Andorra [AD] Telephone: +37 (6) 800-590
Official Contact	Mercedes Roldan, General Manager
Representative/Consultant	Rebecca E. Kattan, PhD Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Email: rkattan@paxmed.com kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Device Name	KLOCKNER KITS
Common Name	Instrument sterilization trays
Regulation Number	21 CFR 880.6850
Regulation Name	Sterilization Wrap
Regulatory Class	Class II
Product Code	KCT
Classification Panel	General Hospital
Reviewing Office	Office of Health Technology 4 (OHT 4: Office of Surgical and Infection Control Devices)
Reviewing Division	Division of Health Technology 4C (Infection Control Devices)

PREDICATE DEVICE INFORMATION

K173642, KLOCKNER Surgical Box, SOADCO, S.L.
K212068, Biotech Dental Kits, Biotech Dental SAS

The primary predicate device is K173642.
The reference device is K212068.

SUBJECT DEVICE INDICATIONS FOR USE STATEMENT

Indications for Use for the KIT WT SNIPER
KLOCKNER KITS are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. KLOCKNER KITS are intended to allow sterilization of the enclosed medical devices.
KLOCKNER KITS require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.
The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Dynamic air removal steam sterilization – Exposure at 134 °C for 4 minutes and 16 minutes dry time.
KLOCKNER KITS are intended for sterilization of non-porous loads.
KLOCKNER KITS are recommended not to be stacked during sterilization.
The combined weight of the KIT WT SNIPER and the associated instruments is 820 grams.
The weight of the empty KIT WT SNIPER is 620 grams.

The KIT WT SNIPER is exclusively indicated to assist in the installation of implants of the VEGA® and ESSENTIAL® CONE 1.5 families and is not compatible with other lines and systems of other manufacturers.

Indications for Use for the KIT WT SNIPER JSI
KLOCKNER KITS are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. KLOCKNER KITS are intended to allow sterilization of the enclosed medical devices.
KLOCKNER KITS require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.
The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Dynamic air removal steam sterilization – Exposure at 134 °C for 4 minutes and 16 minutes dry time.
KLOCKNER KITS are intended for sterilization of non-porous loads.
KLOCKNER KITS are recommended not to be stacked during sterilization.
The combined weight of the KIT WT SNIPER JSI and the associated instruments is 920 grams.
The weight of the empty KIT WT SNIPER JSI is 620 grams.

The KIT WT SNIPER JSI is exclusively indicated to assist in the installation of implants of the VEGA® and ESSENTIAL® CONE 1.5 families and is not compatible with other lines and systems of other manufacturers.

Indications for Use for the KIT WT INTERNA
KLOCKNER KITS are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. KLOCKNER KITS are intended to allow sterilization of the enclosed medical devices.
KLOCKNER KITS require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.
The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Dynamic air removal steam sterilization – Exposure at 134 °C for 4 minutes and 16 minutes dry time.
KLOCKNER KITS are intended for sterilization of non-porous loads.
KLOCKNER KITS are recommended not to be stacked during sterilization.
The combined weight of the KIT WT INTERNA and the associated instruments is 840 grams.
The weight of the empty KIT WT INTERNA is 620 grams.

The KIT WT INTERNA is exclusively indicated to assist in the installation of implants of both the VEGA® and ESSENTIAL® CONE families and is not compatible with other lines and systems of other manufacturers.

Indications for Use for the KIT WT VEGA
KLOCKNER KITS are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. KLOCKNER KITS are intended to allow sterilization of the enclosed medical devices.
KLOCKNER KITS require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.
The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Dynamic air removal steam sterilization – Exposure at 134 °C for 4 minutes and 16 minutes dry time.
KLOCKNER KITS are intended for sterilization of non-porous loads.
KLOCKNER KITS are recommended not to be stacked during sterilization.
The combined weight of the KIT WT VEGA and the associated instruments is 820 grams.
The weight of the empty KIT WT VEGA is 620 grams.

The KIT WT VEGA is exclusively indicated to assist in the installation of implants of the VEGA® family and is not compatible with other lines and systems of other manufacturers.

Indications for Use for the KIT WT ESSENTIAL
KLOCKNER KITS are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. KLOCKNER KITS are intended to allow sterilization of the enclosed medical devices.
KLOCKNER KITS require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.
The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Dynamic air removal steam sterilization – Exposure at 134 °C for 4 minutes and 16 minutes dry time.
KLOCKNER KITS are intended for sterilization of non-porous loads.
KLOCKNER KITS are recommended not to be stacked during sterilization.
The combined weight of the KIT WT ESSENTIAL and the associated instruments is 800 grams.
The weight of the empty KIT WT ESSENTIAL is 620 grams.

The KIT WT ESSENTIAL is exclusively indicated to assist in the installation of implants of the ESSENTIAL® CONE family and is not compatible with other lines and systems of other manufacturers.

Indications for Use for the KIT MEDGUIDE®
KLOCKNER KITS are intended to be used to enclose other medical devices that are to be sterilized by a health care provider. KLOCKNER KITS are intended to allow sterilization of the enclosed medical devices.
KLOCKNER KITS require the use of a wrap that is FDA cleared to maintain the sterility of the enclosed devices.
The kits are to be enclosed in a sterilization wrap that is FDA cleared for the indicated cycles, and moist heat (steam) sterilized using the following cycle: Dynamic air removal steam sterilization – Exposure at 134 °C for 4 minutes and 16 minutes dry time.
KLOCKNER KITS are intended for sterilization of non-porous loads.
KLOCKNER KITS are recommended not to be stacked during sterilization.

The combined weight of the KIT MEDGUIDE® and the associated instruments is 240 grams. The weight of the empty KIT MEDGUIDE® is 160 grams.

The KIT MEDGUIDE® is exclusively indicated to assist in the installation of implants of the VEGA® and ESSENTIAL® CONE families and is not compatible with other lines and systems of other manufacturers.

SUBJECT DEVICE DESCRIPTION

The subject device trays are designed to hold various dental surgical drills and tools to organize and protect the instruments that are sterilized in the tray by the healthcare provider . The base, inner tray, and lid components are designed to be integrated into a single unit (the complete tray) which contains and protects the interior components during sterilization. The lid latches to the base to secure the tray into a single unit. The base, inner tray, and lid components are perforated to allow for penetration of the sterilant, are to be used with moist heat (steam) sterilization and require the use of an FDA cleared wrap to maintain sterility. The subject device components are manufactured from injection molded polysulfone and AISI 316L stainless steel. Holders of various geometries to position instruments in the kits are manufactured from silicone. The subject device trays are summarized in the following table Summary of Tray Dimensions and Contents.

Summary of Tray Dimensions and Contents

[Tray Part Number]/ [Kit Part Number]	Number of items (in Kit)	Enclosed Volume	Total Vent Area	Vent to volume ratio
[20 06 32]/ [KIT WT SNIPER]	69	185.239 in^3	93.41 in^2	0.504 in^2/ in^3
[20 06 33]/ [KIT WT SNIPER JSI]	104	185.239 in^3	93.41 in^2	0.504 in^2/ in^3
[10 06 23]/ [KIT WT INTERNA]	36	185.239 in^3	93.41 in^2	0.504 in^2/ in^3
[10 06 23]/ [KIT WT VEGA]	31	185.239 in^3	93.41 in^2	0.504 in^2/ in^3
[10 06 23]/ [KIT WT ESSENTIAL]	22	185.239 in^3	93.41 in^2	0.504 in^2/ in^3
[10 00 09]/ [KIT MEDGUIDE®]	16	14.280 in^3	2.656 in^2	0.181 in^2/ in^3

TECHNOLOGICAL CHARACTERISTICS COMPARISION DISCUSSION

The subject device and the predicate device K173642 have the same intended use, the same product classification and product code (KCT) and have similar Indications for Use statements. The subject device and the predicate device K173642 are reusable rigid containers used to organize and protect the instruments that are sterilized by the healthcare provider. The subject device and the predicate device K173642 are to be sterilized by moist heat (steam) and require the use of an FDA cleared wrap to maintain sterility. The Indications for Use Statement (IFUs) for the subject device is similar to that of the predicate device K173642 and reference device K212068; slight differences in language of the IFUs do not affect the intended use.

The subject device is provided in 2 sizes and 6 configurations; the predicate device K173642 is provided in 1 size and 1 configuration. The subject device and the predicate device have

similar overall dimensions, enclose similar volumes, and have similar vent to volume ratios. Differences in the dimensions and vent to volume ratios between the subject device and the predicate device are mitigated by the sterilization validation performed.

The reference device, K212068, is provided in 10 sizes and 11 configurations. The subject device and the reference device have very similar overall dimensions, enclose very similar volumes, and have very similar vent to volume ratios. Differences in the dimensions and vent to volume ratios between the subject device and the predicate device are mitigated by the sterilization validation performed.

The basis for the belief of SOADCO, S.L. that the subject device is similar to the predicate device and reference device is summarized in the following Table of Technological Characteristics Comparison.

Table of Technological Characteristics Comparison

	Subject Device		Primary Predicate Device		Refence Predicate Device		Similarity
	K243128 KLOCKNER KITS SOADCO, S.L.		K173642 KLOCKNER Surgical Box SOADCO, S.L.		K212068 Biotech Dental Kits Biotech Dental		
Product Code	KCT		KCT		KCT		Same
Intended Use	organize and protect the devices, instruments, and accessories that are sterilized by health care provider		organize and protect the devices, instruments, and accessories that are sterilized by health care provider		organize and protect the devices, instruments, and accessories that are sterilized by health care provider		
Design	2-piece plastic trays - Rigid polymer base and lid 3-piece plastic trays - Rigid polymer base, lid, and removable inner tray		3-piece plastic trays - Rigid polymer base, lid, and removable inner tray		2-piece plastic trays - Rigid polymer base and lid 3-piece plastic trays - Rigid polymer base, lid, and removable inner tray 2-piece metal trays - Rigid metal base, lid, and inner tray.		Similar
Materials	2-piece plastic trays Polyphenylsulfone (PPSU) [lid/base] 3-piece plastic trays Polyphenylsulfone (PPSU) [lid, base] Polyphenylsulfone (PPSU) + Silicone SE-PX [inner tray]		Injection molding surgical box: - Radel® R-5100 and Radel® R-5800 polymer resin (PPSU – Polyphenylsulfone) - Medical grade silicone - 300 series stainless steel Machined surgical box: - Radel® R PPSU polymer resin - Polypropylene heat stabilized plastic		2-piece plastic trays Polyphenylsulfone (PPSU) (Radel R5000) [lid] Polypropylene (PPHS) [base] 3-piece plastic trays Polyphenylsulfone (Radel R5000) [lid, base, insert] Medical grade silicone [grommets] 2-piece metal trays Stainless Steel AISI 304L Medical grade silicone [grommets]		Same
Materials Compatible with Sterilization Method	Yes		Yes		Yes		Same
Perforated	Yes, allows moist heat (steam) penetration to achieve sterilization		Yes, allows moist heat (steam) penetration to achieve sterilization		Yes; allows moist heat (steam) penetration to achieve sterilization		Same
Number of Overall Sizes	2		1		10		Similar
Number of Configurations	6		1		11		Similar
Overall Dimensions and Vent to Volume Ratio	Length x Width x Height	Vent to Volume Ratio	Length x Width x Height	Vent to Volume Ratio	Length x Width x Height	Vent to Volume Ratio	
	251mm x 156mm x 60.7mm	0.1984 cm^2/cm^3 (0.504 in^2/ in^3)	287.02 mm x 176.02 mm x 55.8 mm (11.3 in x 6.93 in x 2.2 in)	(0.181 in^2/ in^3)	150 mm x 65 mm x 25 mm	0.2260 cm^2/cm^3	Similar
	251mm x 156mm x 60.7mm	0.1984 cm^2/cm^3 (0.504 in^2/ in^3)			150 mm x 65 mm x 25 mm	0.1472 cm^2/cm^3	Similar
	251mm x 156mm x 60.7mm	0.1984 cm^2/cm^3 (0.504 in^2/ in^3)			150 mm x 65 mm x 25 mm	0.3694 cm^2/cm^3	Similar
	251mm x 156mm x 60.7mm	0.1984 cm^2/cm^3 (0.504 in^2/ in^3)			150 mm x 65 mm x 25 mm	0.3932 cm^2/cm^3	Similar
	251mm x 156mm x 60.7mm	0.1984 cm^2/cm^3 (0.504 in^2/ in^3)			125 mm x 127 mm x 24.5 mm	0.1224 cm^2/cm^3	Similar
	120mm x 75mm x 26mm	0.0713 cm^2/cm^3 (0.181 in^2/ in^3)			125 mm x 127 mm x 36.5 mm	0.0346 cm^2/cm^3	Similar
					125 mm x 127 mm x 32.5 mm	0.0567 cm^2/cm^3	
					162.2 mm x 170 mm x 55 mm	0.0049 cm^2/cm^3	

	Subject Device	**Primary Predicate Device**	**Refence Predicate Device**		**Similarity**
	K243128 KLOCKNER KITS SOADCO, S.L.	K173642 KLOCKNER Surgical Box SOADCO, S.L.	K212068 Biotech Dental Kits Biotech Dental		
			162.2 mm x 170 mm x 55 mm	0.0049 cm^2/cm^3	
			162.2 mm x 170 mm x 65 mm	0.0041 cm^2/cm^3	
			40 mm x 50 mm x 20 mm	0.9500 cm^2/cm^3	
Reusable	Yes	Yes	Yes		Same
Use Life Testing	Reusable up to 20 cycles Assembled, sterilized Visual inspection Functional closure (lid-base latch) verification	Reusable up to 101 cycles. Assembled, sterilized Visual inspection	Reusable up to 100 cycles Assembled, sterilized Visual inspection Component dimensional fit verification Functional closure (lid-base latch) verification		Similar
Sterilant	Moist heat (steam)	Moist heat (steam)	Moist heat (steam)		Same
Cycles	Pre-vacuum Steam at 134ºC for 4 minutes with 16 minutes drying time.	Pre-vacuum Steam at 134ºC for 4 minutes with 15 minutes drying time.	Fractionated vacuum (pre-vacuum) Exposure at 132 °C (270 °F) for 4 minutes with 20 minutes drying time.		Similar
Sterile Barrier	Sterilization wrap or pouch, FDA cleared for indicated method and cycle	Sterilization wrap or pouch, FDA cleared for indicated method and cycle	Sterilization wrap or pouch, FDA cleared for indicated method and cycle		Same

SUMMARY OF NONCLINICAL TESTING

Provided below are the nonclinical test methodologies performed to demonstrate the subject devices met the acceptance criteria of the standard.

Summary of Nonclinical Testing Table

Test Methodology	Purpose	Acceptance Criteria	Results
Manual Cleaning Validation FDA Guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* (issued March 2015) ANSI AAMI ST8:2013/(R)2018	The purpose of this test is to validate that the cleaning instructions provided in the Instructions for Use appropriately clean the tray, and to ensure the sterilization cycle will be effective.	Cleaning instructions were validated and demonstrated that the subject devices could be visually and quantifiably cleaned.	Pass
Sterilization Validation including sterilant penetration and dry time validation ANSI/AAMI/ISO 17665-1:2006/(R)2013 ANSI/AAMI/ISO 17665-2:2009	The purpose of this test is to validate that the sterilization instructions listed in the Instructions for Use appropriately sterilize the tray and contents.	3 consecutive half-cycles performed for each of 4 configurations of trays demonstrate complete inactivation of all biologic indicators; A minimum SAL of 10^{-6} is achieved if the Instructions for Use are followed.	Pass
Dry time Validated in Drying Time Validation Report AAMI TIR12: 2020 ANSI/AAMI/ISO 17665-2:2009	The purpose of this test is to validate that the sterilization instructions listed in the Instructions for Use appropriately dry the wrapped tray for storage.	Using pre-cycle and post-cycle weights, the weight gain after drying will be $\leq 3\%$.	Pass
Life Cycle / Simulated Use-life per Validation FDA Guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* (issued March 2015) AAMI TIR12:2020/(R)2023	The purpose of this test is to validate the service life of the trays as stated in the Instructions for Use.	Subject kits were challenged with at least 40 reprocessing cycles. All kits met inspection and performance criteria after 40 uses. For a safety factor of 2X, a maximum of 20 uses is recommended in labeling	Pass
Biocompatibility of Subject Device Cytotoxicity testing ANSI/AAMI/ISO 10993-5:2009/(R)2014 ANSI/AAMI/ISO 10993-12:2012	The purpose of this test is to evaluate the cytotoxicity potential of the test article using an *in vitro* cell culture assay.	The *in vitro* assay performed on the test article showed no reactivity.	Pass

In summary, the nonclinical testing provided for these devices met the acceptance criteria for each standard and test methodology used to evaluate the devices as shown in the table above.

No clinical data were included in this submission.

CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the subject device in this 510(k) submission, KLOCKNER KIT, is as safe, as effective, and perform as well as or better than the legally marketed predicate devices cleared under K173642.