October 2, 2018

Soadco, S.L.
Maria Mitjaneta
Quality Manager
Avgda. Fiter I Rossell, 4 Bis- Local 2
Escaldes-Engordany, AD700 Ad

Re: K173642
Trade/Device Name: Klockner Surgical Box
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: Class II
Product Code: KCT
Dated: July 30, 2018
Received: September 5, 2018

Dear Maria Mitjaneta:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 W. Murray Iii III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): **K173642**

Device Name: Klockner Surgical Box

Indications for Use:

Klockner Surgical Box is a set of sterilization cassettes (thirteen different models between injection molding and machining sterilization cassettes). They all are designed to hold various dental surgical drills, instruments and/or tools in order to organize, steam sterilize and transport the instruments between uses. Their use and handling are intended for physicians and dental professionals in health care or equivalent facilities. The sterilization cassettes have to be enclosed in an FDA-cleared steam sterilizable wrap and sterilized in an FDA-cleared sterilizer according to the following cycle:

- Pre-vacuum Steam at 134ºC for 4 minutes with 15 minutes drying time.

The trays are intended for sterilization of metal and thermoplastic loads.

Klockner Surgical Box includes the following variations of each type of cassette:

Type of cassette	Reference (Ref.)	Device Model Name	Maximum number of instruments / Weight of each container*
Injection molding	**KIT KLOCKNER**	Surgical Box Kit Klockner	80 / 1200 gr.
	KIT INTERNA	Surgical Box Kit Internal®	60 / 1160 gr.
	KIT VEGA	Surgical Box Kit Vega	53 / 1160 gr.
	KIT ESSENTIAL	Surgical Box Kit Essential®	38 / 1120 gr.
	KIT EXTERNA	Surgical Box Kit External®	35/ 1120 gr.
	KIT 20 06 00 ESS	Essential® Guide System Kit	62 / 1180 gr.
Machined	**KIT 10 00 02**	Drill Stop Box Kit	35 / 180 gr.
	KIT 10 00 03	Expansion Box Kit	8 / 200 gr.
	KIT 10 00 04	Regeneration Box Kit	26 / 180 gr.
	KIT 10 00 05	Bone Space Maintainers Box Kit	7 / 180 gr.
	KIT 10 00 06	Pterigomaxilar Box Kit	14 / 216 gr.
	KIT 10 00 07	MedLocate Box Kit	31 / 181 gr.
	KIT 10 00 08	Prosthetic Box Kit	19 / 256 gr.

*Weight of the final product of the Klockner Surgical Box. Full container with all the possible instruments included, wrapped in plastic and included in a corporate carton box which is also wrapped in plastic.

Prescription Use _____ AND / OR Over-The-Counter Use ✓_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

Date of Preparation: 9-28-2018

Submitter name: SOADCO, S.L.
Submitter address: Avgda. Fiter i Rossell, 4bis – Local 2
ESCALDES - ENGORDANY
AD-700 (ANDORRA)
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Device Trade Name: KlocknerSurgical box
Common Name: Instrument Sterilization Tray
Classification Name: Sterilization Wrap

Regulation Number: 21 CFR 880.6850
Class: Class II
Product code: KCT

Legally Marketed (Predicate) Device:

Primary Predicate device 510(k) Number		Device Trade Name	Manufacturer
K142519		InterActive Complete Surgical Tray	Implant Direct Sybron Manufacturing LLC
Reference devices	**510(k) Number**	**Device Trade Name**	**Manufacturer**

1	K012105	PolyVac Surgical Instruments Delivery System	Symmetry Medical Inc.
2	K162063	Steri-Cassette and Steri-Cage Sterilization Packaging Systems	Sybron Dental Specialties Inc.
3	K120947	THS sterilization Tray	Hologic, Inc.

Device Description:

Klockner Surgical Box is a reusable rigid sterilization cassette or organizing tray intended for use in health care facilities for the purpose of containing reusable (and in some cases, non-reusable) devices for sterilization. It is composed of multiple pieces, designed to be integrated into a single unit which contains and protects the interior components during sterilization.

Under the device trade name "*Klockner Surgical Box*", two different sets of sterilization surgical boxes are presented: (Both sets differ in the way the plastic is molded).

- Injection molding sterilization cassettes
- Machined sterilization cassettes

Injection molding Klockner Surgical Box:

Dimensions: 11.3 in x 6.93 in x 2.2 in

Each box consists of three components, a base tray, a locking lid and an internal individualized insert tray. The internal insert tray has the ability to hold individualized pieces and accessories which include dental tools, drills and ratchet. A single box design is available with a size of approximately 11.3 in x 6.93 in x 2.2 inches and it will be marketed in six different kits:

Reference (Ref.)	Device Model Name			
KIT KLOCKNER	Surgical Box Kit Klockner	– containing	80	instruments*

KIT INTERNA	Surgical Box Kit Internal®	– containing	60	instruments*
KIT VEGA	Surgical Box Kit Vega	– containing	53	instruments*
KIT ESSENTIAL	Surgical Box Kit Essential®	– containing	38	instruments*
KIT EXTERNA	Surgical Box Kit External®	– containing	35	instruments*
KIT 20 06 00 ESS	Essential® Guide System Kit	– containing	62	instruments*

*Maximum number of instruments each kit can contain

The lid, base and insert tray are made of Radel® R PPSU (polyphenylsulfone). Radel® R-5800 (violet color) is used for the lid. Radel® R-5100 GY1037 (gray color) is used for the insert tray in two out of the six possible configurations of the surgical box, and Radel® R-5100 BK937 (black color) is used for the base of all configurations and for the insert trays of four of the surgical box variations. the instruments contained in the injection molding Klockner Surgical Box (dental tools, drills and ratchet), are placed in small circular brackets (grommets) located throughout the insert tray. Brackets and holders, are made of medical grade silicone material The lid is locked to the trays with 304 stainless steel latches and both the lid and the trays are silkscreened in white ink with the trade name, trademark and useful information to facilitate the user's use.

The instruments to be sterilized in the injection molding sterilization cassettes are all non-porous devices and include dental surgical drills and tools.

Machined Klockner Surgical Box:

Dimensions: 4.72 in x 2.95 in x 1.79 in and 1.02 in

Each container consists of two parts, a base and a lid. There is not an insert tray in this type of surgical box. Depending on the dental tools and instruments comprised in each kit/variation, there are seven different box designs intended to be commercialized:

Reference (Ref.)	Device Model Name			
KIT 10 00 02	Drill Stop Box Kit	– containing	35	instruments
KIT 10 00 03	Expansion Box Kit	– containing	8	instruments
KIT 10 00 04	Regeneration Box Kit	– containing	26	instruments
KIT 10 00 05	Bone Space Maintainers Box Kit	– containing	7	instruments

KIT 10 00 06	Pterigomaxilar Box Kit	– containing	14	instruments
KIT 10 00 07	MedLocate Box Kit	– containing	31	instruments
KIT 10 00 08	Prosthetic Box Kit	– containing	19	instruments

These seven machined sterilization boxes are available in two sizes depending on the kit. Apart from the Pterigomaxilar Box Kit and the Prosthetic Box Kit which are marketed in a size of 4.72 in x 2.95 in x 1.79 in, the five remaining marketed kits measure 4.72 in x 2.95 in x 1.02 in.

The base is made of PROPYLUX® HS2 heat-stabilized plastic, and the lid is manufactured using TECASON® P VF polyphenylsulfone (PPSU) Smoke. Bases of all seven boxes are laser silkscreened with the trade name, the trademark and useful information for the user. The system that enables to lock the lid to the rest of the box is based on the ability of the lid to slip through two guides that have a burr.

The instruments and dental tools to be sterilized in the machined sterilization cassettes are all non-porous devices.

All the cassettes of Klockner Surgical Box are reusable and the materials allow repeated sterilization cycles. An FDA cleared sterilization wrap must be used for sterilization purposes to maintain the sterility contents.

Intended Use / Indications for Use:

Klockner Surgical Box is a set of sterilization cassettes (thirteen different models between injection molding and machining sterilization cassettes). They all are designed to hold various dental surgical drills, instruments and/or tools in order to organize, steam sterilize and transport the instruments between uses. Their use and handling are intended for physicians and dental professionals in health care or equivalent facilities. The sterilization cassettes must be enclosed in an FDA- cleared steam sterilizable wrap and sterilized in an FDA-cleared sterilizer according to the following cycle:

- Pre-vacuum Steam at 134ºC for 4 minutes with 15 minutes drying time. The trays are intended for sterilization of metal and thermoplastic loads.

Klockner Surgical Box includes the following variations of each type of cassette:

Type of cassette	Reference (Ref.)	Device Model Name	Maximum number of instruments / Weight of each container*
Injection molding	**KIT KLOCKNER**	Surgical Box Kit Klockner	80 / 1200 gr.
	KIT INTERNA	Surgical Box Kit Internal®	60 / 1160 gr.
	KIT VEGA	Surgical Box Kit Vega	53 / 1160 gr.

Type of cassette	Reference (Ref.)	Device Model Name	Maximum number of instruments / Weight of each container*
	KIT ESSENTIAL	Surgical Box Kit Essential®	38/ 1120 gr.
	KIT EXTERNA	Surgical Box Kit External®	35 / 1120 gr.
	KIT 20 06 00 ESS	Essential® Guide System Kit	62 / 1180 gr.
Machined	**KIT 10 00 02**	Drill Stop Box Kit	35 / 180 gr.
	KIT 10 00 03	Expansion Box Kit	8 / 200 gr.
	KIT 10 00 04	Regeneration Box Kit	26 / 180 gr.
	KIT 10 00 05	Bone Space Maintainers Box Kit	7 / 180 gr.
	KIT 10 00 06	Pterigomaxilar Box Kit	14 / 216 gr.
	KIT 10 00 07	MedLocate Box Kit	31 / 181 gr.
	KIT 10 00 08	Prosthetic Box Kit	19 / 256 gr.

*Weight of the final product of the Klockner Surgical Box. Full container with all the possible instruments included, wrapped in plastic and included in a corporate carton box which is also wrapped in plastic.

Summary of Technological Characterics:

Proposed device intended use, indications for use and technological characteristics have been compared with those of the predicates devices (see next pages).

ELEMENT	NEW DEVICE	PRIMARY PREDICATE	REFERENCE DEVICE 1	REFERENCE DEVICE 2	REFERENCE DEVICE 3	**Comparison:** **Subject device vs. Predicate device / Reference devices**
Trade Name	Klockner Surgical Box	InterActive Complete Surgical Tray	PolyVac Surgical Instruments Delivery System	Steri-Cassette and Steri-Cage Sterilization Packaging System	THS sterilization Tray	
Manufacturer	SOADCO,S.L.	Implant Direct Sybron Manufacturing LLC	Poly Vac Inc./ Symmetry Medical Inc.	Sybron Dental Specialties Inc.	Hologic, Inc.	
510 (K)		K142519	K012105	K162063	K120947	
Indications for Use:	Klockner Surgical Box is a set of sterilization	The InterActive Complete Surgical	PolyVac's delivery systems consist of	The Steri-Cassettes and Steri-Cages are	The THS Sterilization Tray is	**Similiar**

	cassettes (thirteen different models between injection molding and machining sterilization cassettes). They all are designed to hold various dental surgical drills, instruments and/or tools to organize, steam sterilize and transport the instruments between uses. Their use and handling are intended for physicians and dental professionals in health care or equivalent facilities. The sterilization cassettes have to be enclosed in an FDA-cleared steam sterilizable wrap and sterilized in an FDA-cleared sterilizer according to the following cycle: Pre-vacuum Steam at 134ºC for 4 minutes with 15 minutes drying time. The trays are intended for sterilization of metal and thermoplastic loads. • and thermoplastic loads.	Tray is designed to hold various dental surgical drills and tools in order to organize, steam sterilize, and transport the instruments between uses. The tray is to be enclosed in an FDA cleared steam sterilizable wrap and sterilized in an FDA cleared sterilizer for one of the following cycles: (1) Prevaccum Steam – At 132 °C for 4 minutes with a 20 minutes dry time. (2) Gravity Steam - At 132 °C for 15 minutes with a 30 minutes dry time.	perforated trays with lids, which are intended to enclose and protect medical device instrumentation, and to facilitate the sterilization process by allowing steam penetration and air removal. When used in conjunction with an approved sterilization wrap, sterility of the enclosed medical device is maintained until used. PolyVac's delivery systems are to be sterilized in one of the following cycles: Prevacuum Steam : 132°C - 4 min Gravity Steam: 132°C - 30 min Gravity Steam: 121°C - 55 minutes	intended to contain dental intruments for cleaning sterilization, organization storage and handling. The Steri-Cassettes and Steri-Cages are suitable for prevacuum and gravity displacement steam sterilization methods. The cassettes and cages are not intended to maintain sterility; they are intended to be used in conjunction with validated, FDA cleared sterilization wrap in order to maintain sterility of the enclosed devices.	used to enclose, protect, and organize the THS scopes, diagnostic sheath, and associated accessory components, and to facilitate the sterilization process by allowing sterilant penetration and air removal when used in conjunction with an approved sterilization wrap. The THS Instrument tray is not designed to maintain sterility by itself, but.when used in conjunction with an approved sterilization wrap sterility of the enclosed medical device is maintained based on the specific time that the maintenance of sterility for that specific wrap as cleared by the FDA.	
Intended use	Perforated instrument cassette system to hold	Perforated instrument cassette system to hold	Perforated trays with lids, which are intended to	Perforated trays with lids to hold surgical	Perforated trays with lids, used to enclose,	**Same**

	dental instruments in place during transport, steam sterilization, and storage when used in conjunction with an approved sterilization wrap.	dental instruments in place during transport, steam sterilization, and storage.	enclose and protect medical device instrumentation, and to facilitate the sterilization process by allowing steam penetration and air removal. When used in conjunction with an approved sterilization wrap, sterility of the enclosed medical device is maintained until used.	instruments in place during transport, steam sterilization, and storage.	protect, and organize the THS scopes, diagnostic sheath, and associated accessory components, and to facilitate the sterilization process by allowing sterilant penetration and air removal when used in conjunction with an approved sterilization wrap.	
Material Composition	<u>Injection molding surgical box</u>: - Radel® R-5100 and Radel® R-5800 polymer resin (PPSU – Polyphenylsulfone) - Medical grade silicone - 300 series stainless steel <u>Machined surgical box</u>: - Radel® R PPSU polymer resin - Polypropylene heat-stabilized plastic	- Radel® R-5000 and Radel® R-5100 (polyphenylsulfone – PPSU) - Medical grade silicone	- Radel® R-5000 plastic - Medical grade silicone - Aluminum - 300 series stainless steel	<u>Cassettes – High Heat</u>: High-Resistant Plastic – Ultem Resin 1000 (proprietary mixture with pigments) (thermoplastic). <u>Cassettes – Standard Heat and cages</u>: polypropylene with color (proprietary mixture with pigments) (*thermoplastic*).	- Radel® R-5000 plastic - Medical grade silicone - 300 series stainless steel	For injection molding boxes, K142519 has the **<u>same</u>** material composition. For machined boxes, K162063 has the **<u>same</u>** material composition.
Reusable	Yes	Yes	Yes	Yes,	Yes	**<u>Same</u>**
Material compatibility with sterilization process	Yes	Yes	Yes	Yes	Yes	**<u>Same</u>**

Summary discussion of non-clinical data:
Validation test for steam sterilization, validation of manual cleaning and limit of reuse test for the Klockner Surgical Box (Surgical Box Kit Klockner and Bone Space Maintainers Box Kit are the containers that represent worst cases) have been carried out as the results are shown by test reports. All tests demonstrated compliance with both safety and effectiveness requirements that apply to the device, in terms of sterilization performance, maintenance of sterility and reusability.
In the following table, **Table 5.1**, a summary of the different performance test carried out and the corresponding standards and results are described.

Table 5.1 Brief description of non-clinical performance testing

Performance Test	Standard(s) used	Results
Cleaning validation	AAMI TIR30:2011 ISO/DIS 19277 / AFNOR-NF S94-091 ISO 11737-1:2006 ISO 9377-2:2000 European Pharmacopoeia ("Method D" from 2.6.14 chapter)	Cleaning instructions were validated and demonstrated that the subject device could be visually and quantifiably cleaned
Steam sterilization validation (Half cycle validation: 2' at 134ºC)	ISO 17665-1:2006 ISO 17665-2:2009 AAMI TIR12:2010 ISO 11737-2:2009	No growth at half cycle
Limits of reuse (Biocompatibility included)	FDA Guideline: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (2011) AAMI TIR12:2010 AAMI TIR30:2011 ISO 10993	the kits were challenged with 101 reprocessing cycles. Both types of sterilization boxes met inspection and performance criteria after 101 reuses.
Drying Time	Validated in Drying Time Validation Report (ISO 17665; AAMI TIR12)	Worst-case loads were determined to be visually and quantifiably dry after exposure to the sterilization cycle and claimed dry time.

Summary Discussion of Clinical Data:
Not applicable.

Conclusions:
Based on the performed nonclinical tests, the device is as safe, as effective, and performs as well as the legally marketed predicate device, **K142519**.