March 2, 2022

Southern Implants (Pty) Ltd
Leith Cumming
Official Correspondent
1 Albert Road
Irene, Gauteng 0062
South Africa

Re: K210923
Trade/Device Name: Southern Implants Instrument Trays
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: Class II
Product Code: KCT
Dated: February 17, 2022
Received: February 18, 2022

Dear Leith Cumming:

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 W. Murray, III, PhD
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

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)*
K210923

Device Name
Southern Implants Instrument Trays

Indications for Use *(Describe)*
The Southern Implants Instrument 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:

- Pre-vacuum Steam – At 132°C for 4 minutes with a 20 minutes dry time.
- Pre-vacuum Steam – At 135°C for 3 minutes with a 20 minutes dry time.

The trays are not intended for sterilization of non-porous loads.
The trays are recommended not to be stacked during sterilization.
The Complete Surgical Trays represent the worst case validated load due to number of components (Large: 25 Medium: 90 and Small: 47 instruments) and the weight (Large: 752; Medium: 672 and Small 339 grams).
Southern Implants (Pty.) Ltd. does not make any lumen claims for the Southern Implants Instrument Trays.

Size (L x W x H)	Product Code	Number of Instruments	Weight of Tray (g)	Weight of Full Tray (g)	Vent to Volume Ratio (in^2/in^3)	For Use With
Large 26.8 x 14.7 x 5.5 cm	CH-I-ZYG	19	485.5	752	0.01	ZAGA Zygomatic Implants (K192651)
	I-ZYG-1	25	485	746	0.01	Zygomatic Implants (K093562; K173343)
Medium 18.7 x 13.5 x 5.5 cm	I-HEX-EG	90	348	672	0.013	External Hex Implants (K163634; K173706; K003620; K020617; K033171; K052490; K070841), Provata Implants (K180465)
	I-DC-EG	53	386	540	0.013	DC Implants (K163060)
	I-INT-HEX-EG	46	392	555	0.013	Provata Implants (K180465)
	I-IT-EG	49	434	541	0.013	IT Implants (K061169)
	I-MAX-EG	50	386	546	0.013	MAX Implants (K071161; K191054)
	I-TRI-NEX-EG	60	390	547	0.013	Tri-Nex Implants (K070905)
Small 14.8 x 9.5 x 5.5 cm	I-PROS-EG	25	180.5	280	0.014	Abutments (K003620; K020617; K033171; K052490; K053478; K061169; K070841; K070905; K071161; K082651; K093562; K163634; K172160; K173343; K173706; K180465; K181850; K191054; K191250; K192651; K193084)
	I-PROS-MINI	7	122.5	147	0.056	
	I-IV-EG	47	228	339	0.013	Inverta Implants (K181850)

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.

510(k) Summary

Southern Implants Instrument Trays

28/02/2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	Southern Implants (Pty) Ltd 1 Albert Road Irene, Gauteng, 0062 South Africa Telephone: +27 12 667 1046 Fax: +27 12 667 1029
Official Contact	Leith Cumming Acting Head of Regulatory Affairs and Quality Email: leith.c@southernimplants.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Southern Implants Instrument Trays
Common Name	Instrument Trays
Classification Name	Sterilization Wrap Containers, Trays, Cassettes and other Accessories
Classification Regulation	21 CFR 880.6850, Class II
Product Code	KCT
Classification Panel	General Hospital
Reviewing Branch	General Hospital

PREDICATE DEVICE INFORMATION

The primary predicate device is K142519
The reference device is K182865.

INDICATIONS FOR USE STATEMENT

The Southern Implants Instrument 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:

- Pre-vacuum Steam – At 132°C for 4 minutes with a 20 minutes dry time.
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The trays are not intended for sterilization of non-porous loads.

The trays are recommended not to be stacked during sterilization.

The Complete Surgical Trays represent the worst case validated load due to number of components (Large: 25 Medium: 90 and Small: 47 instruments) and the weight (Large: 752; Medium: 672 and Small 339 grams).

Southern Implants (Pty.) Ltd. does not make any lumen claims for the Southern Implants Instrument Trays.

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	I-ZYG-1	25	485	746	0.01	Zygomatic Implants (K093562; K173343)
Medium 18.7 x 13.5 x 5.5 cm	I-HEX-EG	90	348	672	0.013	External Hex Implants (K163634; K173706; K003620; K020617; K033171; K052490; K070841) Provata Implants (K180465)
	I-DC-EG	53	386	540	0.013	DC Implants (K163060)
	I-INT-HEX-EG	46	392	555	0.013	Provata Implants (K180465)
	I-IT-EG	49	434	541	0.013	IT Implants (K061169)
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	I-PROS-MINI	7	122.5	147	0.056	K061169; K070841; K070905; K071161; K082651; K093562; K163634; K172160; K173343; K173706; K180465; K181850; K191054; K191250; K192651; K193084)
	I-IV-EG	47	228	339	0.013	Inverta Implants (K181850)

SUBJECT DEVICE DESCRIPTION

The device 'instrument trays' is a reusable rigid sterilization container or organizing tray intended for use in health care facilities for the purpose of containing reusable medical 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. Each tray consists of three components: a base tray, a lid and an internal individualized insert tray. All three the components are perforated for steam sterilization. The internal insert tray and base has the ability to hold individualized pieces and accessories which include dental tools, drills and ratchets /wrenches.

The lid, base and insert are made of Radel R-5000. This material is a polymer resin.

The instruments to be sterilized in the proposed tray are all non-porous devices and include dental surgical drills and tools.

The rigid multi-piece tray holds dental device apparatus and accessories before, during and after the sterilization process. The tray set has a locking lid to contain the products. The trays are designed to fit any standard autoclave, which allows it to be effective for sterilization and be able to withstand the environment of repeated steam sterilization and be able to withstand the environment of repeated steam sterilization cycles in normal operating room. Since the trays are perforated, an FDA cleared sterilization wrap mush be used for sterilization purposes to maintain the sterility of the contents

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the subject device and the primary predicate device K142519 is provided in the following table.

Table 1: Technological Characteristics Comparison

Comparison	Subject Device	Primary Predicate Device	Comparison
	Instrument Trays **Southern Implants (Pty) Ltd**	**K142519** **InterActive Complete Surgical Tray** **Implant Direct Sybron Manufacturing LLC**	
Indications for Use Statement	The Southern Implants Instrument 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:	The InterActive Complete Surgical 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:	Same
Product Code	KCT	KCT	Same
Intended Use	Perforated instrument cassette system to hold dental instruments in place during transport, steam sterilization, and storage.	Perforated instrument cassette system to hold dental instruments in place during transport, steam sterilization, and storage.	Same
Material Composition	Polymer Resin Radel-5000, biomedical grade silicone, surgical grade stainless steel	Polymer Resin Radel-5000, biomedical grade silicone	Same
Design	Plastic tray with locking lid; silicone containment brackets and stainless-steel holder	Plastic tray with locking lid and silicone containment brackets	Similar
Sterilization by: 1. Gravity Steam 2. Pre-vacuum Steam 132°C Pre-vacuum Steam 135°C	 No Yes Yes	 Yes Yes No	Similar for pre-vacuum.
Air Permeance	Yes	Yes	Same
Locking system to hold lid in place	Yes	Yes	Same
Reusable	Yes	Yes	Same
Material compatibility with sterilization process	Yes	Yes	Same
Sterilant Penetration Studies	Yes – Steam sterilization validation conducted per ISO 17665; AAMI TIR 12	Yes – Steam sterilization validation conducted per AAMI / ANSO / ISO17665; AAMI TIR 12	Same
Toxicological Properties (biocompatibility)	Yes – Cytoxicity tests conducted as per ISO 10993-5; ISO 10993-12	Yes – Cytoxicity tests conducted as per ISO 10993-5; ISO 10993-12	Same
Transportation Studies	Yes – Distribution studies conducted as per ASTM D4169	Yes – Distribution studies conducted as per ASTM D4169	Same
Cleaning Instructions for Reusable devices	Cleaning validations conducted as per AAMI TIR 30, AAMI TIR 12.	Cleaning validations conducted as per AAMI TIR 30, AAMI TIR 12.	Same
Material Compatibility (repeat validation)	Yes – Radel Technical Data Sheet	Yes – Radel Technical Data Sheet	Same
Drying Time	Yes – Steam sterilization validation conducted per AAMI 17665; AAMI TIR 12	Yes – Steam sterilization validation conducted per AAMI 17665; AAMI TIR 12	Same
Vent/Volume Ratio in^2 / in^3	Large: 0.01 Medium: 0.013 – 0.014 Small: 0.014 – 0.056	0.184	Different
Maximum Sterilization Load density (g/cm^3)	Large: 0.533 Medium: 0.532 Small: 0.397	0.375	Different
Dimensions (L x W x H) (cm)	Large: 26.8 x 14.7 x 5.5 Medium: 18.7 x 13.5 x 5.5	19 x 14.2 x 6	Different

	Small: 14.8 x 9.5 x 5.5		
Maximum weight of tray with instruments	Large: 752 Medium: 672 Small: 339	608.05	Different
Maximum number of components	Large: 25 Medium: 90 Small: 47	45	Different

The Indications for Use Statement for the subject device is similar to the primary predicate device K142519, with the difference being the name of the device

The primary predicate device K142519 is for comparison to the subject device implant designs. The subject device Southern Implants Instrument Trays have a design that similar in design to trays in K142519. The subject device is also similar to the predicate device with regards to the intended use; the material composition; sterilization method; cleaning instruction validation and toxicological properties.

PERFORMANCE DATA

Provided below in Table 2 is the summary of the non-clinical testing that was performed per specification of the standard and test methodology listed below. The results of the performance testing demonstrated the subject device met the acceptance criteria of the standard and the test methodology.

Table 2: Summary of Non-Clinical Testing

Test Methodology	Purpose	Acceptance Criteria	Results
ISO 17665-1 *Sterilization of health care products – moist*	To verify the ability of the sterilization process to adequately sterilize	6 log reduction at half cycle	The ability for successful sterilization

heat – part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	the load at 132°C and 135°C		at 132°C and 135°C was confirmed
ISO 17664 *Processing of health care products – information to be provided by the medical device manufacturer for the processing of medical* devices AAMI TIR 12 *Designing, testing, and labelling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers* AAMI TIR 30 *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*	To verify the effectiveness of the recommended cleaning process.	Protein < 6 µg/ml Hemoglobin < 100 mg /ml	The recommended cleaning process is effective.
ISO 10993-5 *Biological Evaluation of Medical Device – part 5: Tests for in-vitro cytotoxicity*	To observe the cytotoxicity potential of the device	Morphological grade 2	No cytotoxicity potential was observed.
ASTM D 4169 (2007) *Standard practice for performance testing of shipping containers and systems*	To verify the durability of the device during transportation.	No damage to the tray.	The instrument trays survived transit and transport conditions.
Temperature distribution control	To verify the homogeneity of the temperature distribution inside the tray	There must be no areas colder than the specified temperature	Temperature was homogenous.

CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the Southern Implants Instrument Trays are as safe, as effective and performs as well as or better than the legally marketed device K142519 InterActive Complete Surgical tray.