August 16, 2023

Implant Direct Sybron Manufacturing, LLC
Reina Choi
Regulatory Affairs Manager
3050 East Hillcrest Drive
Thousand Oaks, California 91362

Re: K231087
Trade/Device Name: Guided Surgery Kit
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: DZI, KCT
Dated: May 18, 2023
Received: May 19, 2023

Dear Reina Choi:

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,

Michael E. Adjodha -S

Michael Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K231087

Device Name

Guided Surgery Kit

Indications for Use *(Describe)*

The Guided Surgery Kit is designed to hold various dental surgical drills and instruments to organize, steam sterilize, and transport between uses. The guided surgical drills are intended to cut into maxilla or mandible to create an osteotomy for endosseous dental implant placement.

The kit is to be enclosed in a FDA cleared steam sterilizable wrap (maximum thickness KC300) and sterilized in a FDA cleared sterilizer for one of the following cycles:

(1) Prevacuum Steam – At 132°C for 4 minutes with a 20 minute dry time.
(2) Gravity Steam – At 132°C for 15 minutes with a 30 minute dry time.

- The kit is intended for sterilization of non-porous loads.
- Do not stack kits during sterilization.
- Implant Direct Sybron Manufacturing LLC does not make any lumen claims for the Sterilizable Guided kit.

Model Name	Model Number	Max # of Instruments	Mass (g)	Vent to Volume Ratio (in-1)
Guided Surgical Kit - Legacy	GSK-L	51	446.52	0.032
Guided Surgical Kit – Conical	GSK-C	48	442.01	0.033
Guided Surgical Kit - Empty	GSK-E	N/A	299.94	0.033

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 – K231087

i. Submitter Information

Submitter:	Implant Direct Sybron Manufacturing, LLC 3050 E. Hillcrest Drive Thousand Oaks, CA 91362, USA
Contact Person:	Reina Choi, Sr. Regulatory Affairs Manager
E-Mail:	Reina.choi@envistaco.com
Telephone Number:	(818) 307-3132
Prepared By:	Reina Choi, Sr. Regulatory Affairs Manager
Date Prepared	August 15, 2023

ii. Device Name

Proprietary name:	Guided Surgery Kit
Manufacturer:	Implant Direct Sybron Manufacturing, LLC
Common Name:	Endosseous Dental Implant Drills
Classification Name:	Bone cutting instrument and accessories
Regulation Number:	21 CFR 872.4120
Device Class:	II
Primary Product Code:	DZI
Secondary Product Code:	KCT

iii. Predicate Devices

Predicate Device

510(k) #:	K200265
Propriety Name:	Surgical Drills
Manufacturer:	Implant Direct Sybron Manufacturing, LLC
Common Name:	Endosseous Dental Implant Drills
Classification Name:	Bone cutting instrument and accessories
Regulation Number:	21 CFR 872.4120
Device Class:	Class II
Product Code:	DZI

Reference Device

510(k) #:	K202524
Propriety Name:	Standard Sterilizable Tray
Manufacturer:	Implant Direct Sybron Manufacturing, LLC
Common Name:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Classification Name:	Sterilization Wrap
Regulation Number:	21 CFR 880.6850
Device Class:	Class II
Product Code:	KCT

iv. Device Description

The Guided Surgery Kit is offered in 2 complete kit variations for 3 implant systems: Legacy, Simply Iconic, and InterActive as a reusable perforated tray for purposes of transport, steam sterilization and storage of dental instruments, similar to the reference device Standard Sterilizable Tray (K202524). The kit is sold non-sterile and contains site preparation instruments, dental drills, implant driving tools, prosthetic driving tools and ratchet tool which can be used for implant placement. The proposed Guided Surgical Drills are reusable surgical instruments designed to prepare an osteotomy for a dental implant procedure. The features remain unchanged from the predicate Surgical Drills (K200265) except for the addition of a Guide Body and Shoulder Stop. The addition of a Guide Body allows the proposed drills to function with guide sleeves which can be integrated into an existing surgical guide template to assist in the drilling sequence and placement of dental implants.

Note: The guide sleeves are not included in the scope of the clearance.

v. Principle of Operation / Mechanism of Action

The principal of operation is based on the placement of a Sleeve over an existing surgical guide template which allows all the instruments within the guided surgery kit to be guided for position, angulation, and depth. The instruments found in the guided surgery kit share a common Guide Hub that has a Shoulder to act as a Stop. The Guided Drill is inserted into the Sleeve and the Guide Body portion of the Drill engages with the Sleeve prior to patient contact. Once the Guide Body is engaged with the Sleeve the Drill is now Guided to aid in drilling the osteotomy until the Shoulder contacts the Sleeve which prevents the drill from drilling too deep. Once the osteotomy drilling is complete, the same Sleeve can be immediately used with the Guided Driver which drives the implant into the planned site.

vi. Compatible Devices and Accessories

The Guided Surgery Kit is intended to be used with previously cleared or exempt accessories/devices from Implant Direct.

vii. Patient Contacting Components

Following the assessment set forth in ISO 10993-1:2018 Biological Evaluation of Medical Devices, Annex A, it was determined that the devices in scope of this submission do contain patient contacting components. The patient contacting components have direct patient contact for (≤ 24 hours and typically less than five (5) minutes in single clinical application to complete the surgical procedure).

Table 0-2 – Patient Contacting Materials

Product Name	Material Description	Colorant
Dental Drills	Stainless Steel 455 per ASTM F899 with Diamond Like Coating (DLC)	N/A

viii. Indications for Use

The Guided Surgery Kit is designed to hold various dental surgical drills and instruments to organize, steam sterilize, and transport between uses. The guided surgical drills are intended to cut into maxilla or mandible to create an osteotomy for endosseous dental implant placement.

The kit is to be enclosed in a FDA cleared steam sterilizable wrap (maximum thickness KC300) and sterilized in a FDA cleared sterilizer for one of the following cycles:

(1) Prevacuum Steam – At 132°C for 4 minutes with a 20 minute dry time.
(2) Gravity Steam – At 132°C for 15 minutes with a 30 minute dry time.

- The kit is intended for sterilization of non-porous loads.
- Do not stack kits during sterilization.
- Implant Direct Sybron Manufacturing, LLC does not make any lumen claims for the Sterilizable Guided kit.

Model Name	Model Number	Max # of Instruments	Mass (g)	Vent to Volume Ratio (in^{-1})
Guided Surgical Kit - Legacy	GSK-L	51	446.52	0.032
Guided Surgical Kit – Conical	GSK-C	48	442.01	0.033
Guided Surgical Kit - Empty	GSK-E	N/A	299.94	0.033

ix. Summary of Substantial Equivalence

The similarities and differences between the Subject Device, Guided Surgery Kit and the Predicate Devices as described in Table 0-3 are as follows:

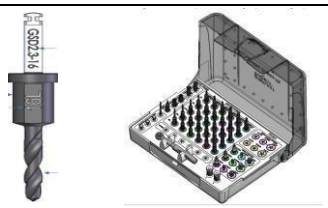
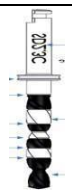
The similarities between the Guided Surgery Kit (Subject Device), Predicate Device Surgical Drills (K200265) and Reference Device Standard Sterilizable Tray (K202524), listed in the table below are the Indications for Use, Mode of Action, material, and general design features. Exterior dimensions, surface finish, and mated surface of kit lid opens/closes via side hinges on the kit are the same. Also, Biocompatibility testing, Cleaning and Sterilization validation testing are the same.

There are no major differences however there are minor differences between the Guided Surgery Kit (Subject Device) and Predicate Device Surgical Drills and Reference Device Standard Sterilizable Tray as follows:
1) subject device has additional integrated guided body and guide hub compared to predicate; 2) subject device has DLC coating covering the entire cutting flutes area, while predicate is only partially coated with DLC; 3) subject device has same outer tray dimensions and slight different inner tray layout from reference device; 4) subject device has larger maximum number of instruments, but smaller maximum sterilization load compared to reference device; 5) subject device has larger vent to volume ratio than reference device; 6) the total number of instruments surface area of the subject device is slightly larger by 3% than the reference device.

Conclusion:

Based on a comparison of intended use, indications for use, technological characteristics, principle of operation, features, and performance data, the Guided Surgery Kit is deemed to be substantially equivalent to the predicate devices as it satisfies all criteria of substantial equivalence and does not raise new concerns regarding substantial equivalence: (1) Indications for Use, (2) Technological Characteristics, and (3) Performance Data. The new device does not introduce a fundamentally new scientific technology and the nonclinical tests demonstrate that the device is substantial equivalent.

Table 0-3: Guided Surgery Kit Comparison Table

Description	**<u>Subject Device</u> Guided Surgery Kit**	**<u>Predicate</u> Surgical Drills (K200265)**	**<u>Reference Device</u> Standard Sterilizable Tray (K202524)**	**Comparison**
Manufacturer	Implant Direct	Implant Direct	Implant Direct	Same
Pictorial Representation				N/A
Regulatory Classification				
Regulation #	21 CFR 872.4120 21 CFR 880.6850	21 CFR 872.4120	21 CFR 880.6850	Same
Regulation Title	Bone cutting instrument and accessories; Sterilization Wrap	Bone cutting instrument and accessories	Sterilization Wrap	Same
Regulation Class	II	II	II	Same
Product Code	DZI, KCT	DZI	KCT	Same
Indications for Use/Intended Use				
Indications for Use / Intended Use	The Guided Surgery Kit is designed to hold various dental surgical drills and instruments to organize, steam sterilize, and transport between uses. The guided surgical drills are intended to cut into maxilla or mandible to create an osteotomy for endosseous dental implant placement. The kit is to be enclosed in an FDA cleared steam sterilizable wrap (maximum thickness KC300) and sterilized in an FDA cleared sterilizer for one of the following cycles: (1) Prevacuum Steam – At 132°C for 4 minutes with a 20 minute dry time. (2) Gravity Steam – At 132°C for 15 minutes with a 30 minute dry time. • The kit is intended for sterilization of non-porous loads. • Do not stack kits during sterilization. • Implant Direct Sybron Manufacturing LLC does not make any lumen claims for the Guided Surgery Kit	The Surgical Drills are intended to cut into maxilla or mandible to create an osteotomy for endosseous dental implant placement.	The Standard Sterilizable Tray is designed to hold various dental surgical and prosthetic instruments 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 (maximum thickness KC300) and sterilized in an FDA cleared sterilizer for one of the following cycles: (1) Prevacuum 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. - The tray is intended for sterilization of non-porous loads. - Do not stack trays during sterilization. - The tested Tray represents the worst case validated load of 667.52 grams. - Implant Direct Sybron Manufacturing LLC does not make any lumen claims for the Standard Sterilizable Tray.	Same as Predicate and Reference Device, except subject device has larger # of instruments, smaller max load, and larger vent to volume ratio.

Model Name	**Model #**	**Max # of Instruments**	**Max Load (g)**	**Vent to volume Ratio (in^{-1})**

Model Name	**Model #**	**Max # of Instruments**	**Max Load (g)**	**Vent to volume Ratio (in^{-1})**

Description	Subject Device Guided Surgery Kit	Predicate Surgical Drills (K200265)	Reference Device Standard Sterilizable Tray (K202524)	Comparison
	Guided Surgery Kit - Legacy: GSK-L, 51, 446.52, 0.032 Guided Surgery Kit - Conical: GSK-C, 48, 442.01, 0.033 Guided Surgery Kit - Empty: GSK-E, N/A, 299.94, 0.033		Standard Surgical Kit: CSSK, 46, 667.52, 0.021 Standard Surgical Kit Empty: SSK, , 385.2, 0.021 InterActive Surgical Kit: CISK, 34, 662.70, 0.021 InterActive Surgical Kit Empty: ISK, , 384.2, 0.021	
Technological Characteristics				
Drill General Design	Multiple cutting edges and flutes to create an osteotomy. Shank to fit with hand piece.	Multiple cutting edges and flutes to create an osteotomy. Shank to fit with hand piece.	N/A	Same as predicate
Drill Material	Stainless Steel	Stainless Steel	N/A	Same as predicate
Drill Coating	DLC (Diamond Like Coating)	No Coating or DLC (Diamond Like Coating)	N/A	Same as predicate
Kit General Design	Plastic tray with locking lid co-molded silicone and silicone grommet	N/A	Plastic tray with locking lid co-molded silicone and silicone grommet	Same as reference
Kit Material	Radel R-5000 polyphenylsulfone	N/A	Radel R-5000 polyphenylsulfone	Same as reference
Kit Dimensions	190mm X 145mm X 68mm	N/A	190mm X 145mm X 68mm	Same as reference
Surface Finish	63 µin	N/A	63 µin	Same as Predicate
Mated surface via side hinges	Yes	N/A	Yes	Same as Predicate
Sterility	Non-sterile	Non-sterile	Non-sterile	Same
Vent to Volume Ratio	GSK-L: 0.032 (in^{-1}) GSK-C: 0.033 (in^{-1}) GSK-E: 0.033 (in^{-1})	N/A	0.021 (in^{-1})	Similar to reference
Reusable or single use	Reusable	Reusable	Reusable	Same
Performance Testing				
Biocompatibility	ISO 10993-1:2018	ISO 10993-1:2018	ISO 10993-1:2018	Same
Sterilization Validation	ISO 17665-1:2006	ISO 17665-1:2006	ISO 17665-1:2006	Same

x. Performance Testing Data

Non-clinical Test

Non-clinical testing was evaluated on the Subject device Guided Surgery Kit:

- Verification of biocompatibility of the final device in accordance with ISO 10993-1 and the results demonstrated the subject device is biocompatible.
- Cleaning and Steam sterilization validation in accordance with AAMI TIR12 and ISO 17665-1 and the results demonstrated the subject device can achieve a SAL of 10^{-6}.
- Performance testing (i.e., scratch test, SEM analysis, etc.) with comparative analysis of the critical dimensions of the design characteristics of the worst-case drill included in the scope of the submission and predicate device submission.

Clinical Performance Data:

Clinical performance data is not required to establish substantial equivalence for the subject device.

xi. Conclusion

Based on a comparison of indications for use, material composition, technological characteristics, principle of operation, features and performance data, the Guided Surgery Kit is deemed to be substantially equivalent to the Predicate Devices.