



February 6, 2026

Dentsply Sirona Inc.
Laura Sobrin
Sr. Technical RA Manager
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K251614

Trade/Device Name: Stainless Steel Surgical Kits
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: January 5, 2026
Received: January 5, 2026

Dear Laura Sobrin:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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: 2026.02.06
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Stephen Anisko
Acting 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

Indications for Use

510(k) Number (if known)
K251614

Device Name
Stainless Steel Surgical Kits

Indications for Use (Describe)

Stainless Steel Surgical Kits

- The Stainless Steel Surgical Kits are intended for organizing, sterilizing and storing of drills, instruments, and prosthetic accessories.
- The Stainless Steel Surgical Kits are not intended to maintain sterility and are to be used in conjunction with a legally marketed, validated sterilization pouch.

Sterilization parameters

- Pre-vacuum Steam at 132 °C (270 °F) for 4 minutes with a 20 minute dry time.
- Do not exceed the worst-case validated maximum load:

Item Number	Product Name	Dimensions (inch)	Max Load (gr)	Vent to Volume Ratio (inch-1)	Kit type
MK-0020	Bone compression kit	3.94x3.46x1.86	318.77	0.15	Closed
MK-0056	Scan post Int. Hexagon connection Kit	2.60x2.83x1.02	143.59	0.29	Closed
MK-0057	Scan post Conical connection Kit	2.60x2.83x1.02	146.32	0.29	Closed
MK-0059	Bone profiler Int. Hex. kit	2.79x1.18x1.77	79.26	10.18	Open
MK-0060	Bone profiler con. con. kit	2.79x1.18x1.77	81.00	10.18	Open
MK-0065	Scan post organizer box	2.60x2.83x1.02	146.32	0.29	Closed
MK-BC101	Drill stopper kit for C1 implant, SP	2.60x2.83x1.02	144.87	0.29	Closed
MK-BS001	Drill stopper kit for Seven implant, SP	2.60x2.83x1.02	144.64	0.29	Closed
MK-CDS08	Drill stopper kit for 8mm length C1 implant procedure	1.97x2.83x1.02	117.27	0.26	Closed
MK-CDS10	Drill stopper kit for 10mm length C1 implant procedure	1.97x2.83x1.02	116.70	0.26	Closed
MK-CDS11	Drill stopper kit for 11.5mm length C1 implant procedure	1.97x2.83x1.02	116.28	0.26	Closed
MK-CDS13	Drill stopper kit for 13mm length C1 implant procedure	1.97x2.83x1.02	115.86	0.26	Closed
MK-LDSK	Lance Drill stoppers kit	4.22x3.96x1.20	282.17	0.20	Closed
MK-SDS06	Drill stopper kit for 6mm length Seven implant procedure	1.97x2.83x1.02	118.43	0.26	Closed
MK-SDS08	Drill stopper kit for 8mm length Seven implant procedure	1.97x2.83x1.02	117.19	0.26	Closed
MK-SDS10	Drill stopper kit for 10mm length Seven implant procedure	1.97x2.83x1.02	116.64	0.26	Closed
MK-SDS11	Drill stopper kit for 11.5mm length Seven implant procedure	1.97x2.83x1.02	116.22	0.26	Closed
MK-SDS13	Drill stopper kit for 13mm length Seven implant procedure	1.97x2.83x1.02	115.81	0.26	Closed

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 for
Stainless Steel Surgical Kits, K251614**

1. Submitter Information:

Dentsply Sirona Inc.
221 West Philadelphia Street
Suite 60W
York, PA 17401

Contact Person: Laura Sobrin
Telephone Number: 717-849-4434
Email: laura.sobrin@dentsplysirona.com
Date Prepared: February 4, 2026

2. Device Name:

- Proprietary Name: Stainless Steel Surgical Kits
- Classification Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
- CFR Number: 21 CFR 880.6850
- Device Class: Class II
- Product Code: KCT

3. Predicate and Reference Devices:

The predicate and reference devices identified are the following:

Type of Device	Device Name	510(k)	Company Name
Predicate	Surgical and Prosthetic Trays	K220791	Dentsply Sirona Inc.
Reference	Washtrays	K231144	Dentsply Sirona Inc.
Reference	Biotech Dental Kits	K212068	Biotech Dental, SAS

4. Device Description:

The Stainless Steel Surgical Kits are reusable containers that are used to store and organize drills, instruments, and prosthetic accessories needed before, during and after the implantation and the prosthetic procedure.

The Stainless Steel Surgical Kits are also designed to hold the drills, instruments, and prosthetic accessories during the sterilization process. The kits are intended to be used in conjunction with a legally marketed, validated sterilization pouch that is intended to maintain sterility of the items placed inside the kits.

The proposed Stainless Steel Surgical Kits must be cleaned and sterilized before the first use and after each use according to the Instructions for Use (IFU) included with each kit.

The proposed Stainless Steel Surgical Kits can be divided into two types of kits: Open and Closed Kits.

Open kits consist of a lid and base with holders. Open kits cannot be closed with a lid to cover the items, but contain a lid that is always open and can be moved to a horizontal position. Open kits also do not contain an insert; the instrument holders are integrated on the base of the kit. In addition, in Open kits, the base is open and the holders can be seen through the bottom of the base.

By contrast, Closed kits consist of a lid, removable insert with holders, and base. Closed kits have a lid that can be closed. The lid has perforations that allows for steam penetration. In addition, one of the proposed Closed kits also contains a removable bath. The bath is used to hold soiled items after use during the surgical procedure.

The lid, base, insert, and bath of these kits are made of stainless steel. Silicone holders hold the kit components in each surgical kit. The role of the holders is to properly hold the items during transportation, sterilization and before use by the dentist.

5. Intended Use and Indications for Use

Stainless Steel Surgical Kits

- The Stainless Steel Surgical Kits are intended for organizing, sterilizing and storing of drills, instruments, and prosthetic accessories.
- The Stainless Steel Surgical Kits are not intended to maintain sterility and are to be used in conjunction with a legally marketed, validated sterilization pouch.

Sterilization parameters

- Pre-vacuum Steam at 132 °C (270 °F) for 4 minutes with a 20 minute dry time.
- Do not exceed the worst-case validated maximum load:

Item Number	Product Name	Dimensions (inch)	Max Load (gr)	Vent to Volume Ratio (inch-1)	Kit type
MK-0020	Bone compression kit	3.94x3.46x1.86	318.77	0.15	Closed
MK-0056	Scan post Int. Hexagon connection Kit	2.60x2.83x1.02	143.59	0.29	Closed
MK-0057	Scan post Conical connection Kit	2.60x2.83x1.02	146.32	0.29	Closed
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MK-CDS08	Drill stopper kit for 8mm length C1 implant procedure	1.97x2.83x1.02	117.27	0.26	Closed
MK-CDS10	Drill stopper kit for 10mm length C1 implant procedure	1.97x2.83x1.02	116.70	0.26	Closed
MK-CDS11	Drill stopper kit for 11.5mm length C1 implant procedure	1.97x2.83x1.02	116.28	0.26	Closed
MK-CDS13	Drill stopper kit for 13mm length C1 implant procedure	1.97x2.83x1.02	115.86	0.26	Closed
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MK-SDS10	Drill stopper kit for 10mm length Seven implant procedure	1.97x2.83x1.02	116.64	0.26	Closed

Item Number	Product Name	Dimensions (inch)	Max Load (gr)	Vent to Volume Ratio (inch-1)	Kit type
	procedure				
MK-SDS11	Drill stopper kit for 11.5mm length Seven implant procedure	1.97x2.83x1.02	116.22	0.26	Closed
MK-SDS13	Drill stopper kit for 13mm length Seven implant procedure	1.97x2.83x1.02	115.81	0.26	Closed

6. Comparison of Technological Characteristics

The proposed Surgical Kits have the same intended use, similar Indications for Use, and incorporate the same fundamental technology as the predicate device, Surgical and Prosthetic Trays (K220791), with similar general design and functionality.

The proposed and predicate (K220791) devices share the same sterilization method (pre-vacuum) and sterilization parameters. Both devices are intended to be used with an FDA cleared sterilization single pouch.

Both the proposed and predicate devices are reusable. The difference in reuse life is based on the number of cycles validated (50 cycles) for the proposed kits when compared to the cycles validated on the predicate device (200 cycles).

An overview of the similarities and differences between the proposed, predicate, and reference devices is given in Table 6.1.

Table 6.1: Similarities and Differences between the proposed, predicate, and reference devices

Element	Proposed Device Stainless Steel Surgical Kits	Predicate Device Surgical and Prosthetic Trays (K220791)	Reference Device Washtrays (K231144)	Reference Device Biotech Dental Kits 2-piece metal trays (K212068)	Comparison
Manufacturer	MIS Implants Technologies Ltd. (part of Dentsply Sirona)	Dentsply Implants Manufacturing GmbH (part of Dentsply Sirona)	Dentsply Implants Manufacturing GmbH (part of Dentsply Sirona)	Biotech Dental, SAS	Same corporation for the predicate and reference (K231144) device
Intended Use	Intended for organizing, sterilizing and storing of drills, instruments, and prosthetic accessories	Intended for organizing, sterilizing and storing of instruments	Intended for organizing, cleaning, sterilizing, and storing of instruments	Intended to allow sterilization of the group medical devices	Same general intended use as the predicate device.
Product code	KCT	KCT	KCT	KCT	Same
Regulation #	21 CFR 880.6850	21 CFR 880.6850	21 CFR 880.6850	21 CFR 880.6850	Same
General design and Components	<p>Closed kit: Perforated stainless steel box (lid and base) with removable stainless steel insert, on which holders made of silicone are assembled. One kit contains a removable stainless steel bath.</p> <p>Open Kit: Stainless steel kit (lid and base) without an insert. The base integrates the silicone holders.</p>	Perforated plastic box (lid and base) with removable plastic insert, on which holders made of silicone are assembled. The base also holds instruments.	Perforated stainless steel box (lid and base) which incorporates a small stainless steel basket, and an anodized aluminum insert with large stainless steel basket underneath. The insert contains thermoplastic holders with stainless steel springs, and the small basket contains a silicone mat.	2 piece stainless steel tray with silicone holders	<p>Similar general design and components.</p> <p>The proposed (Closed) Stainless Steel Surgical Kits and the predicate device (K220791) have the same components: lid, base, insert and holders. One of the proposed Stainless Steel Surgical Kits contains an additional bath component.</p> <p>For Closed kits, the lid and base have ventilation apertures (i.e. perforations) and the insert is a perforated plate mounted on the base, which is similar to the</p>

Element	Proposed Device Stainless Steel Surgical Kits	Predicate Device Surgical and Prosthetic Trays (K220791)	Reference Device Washtrays (K231144)	Reference Device Biotech Dental Kits 2-piece metal trays (K212068)	Comparison
					<p>predicate device (K220791). The holders are assembled in the insert, and they hold the items in place.</p> <p>The difference is that predicate device (K220791) allows for placement of items in the base, whereas the proposed Stainless Steel Surgical Kits hold all items within the insert only.</p> <p>The proposed Open kits are similar to the reference device K212068 in design concept and materials.</p> <p>The reference device K231144 also shares similar materials compared to the proposed Closed kits, which is also a perforated kit.</p>
Dimensions (inch)	1.97 x 2.83 x 1.02 2.60 x 2.83 x 1.02 2.79 x 1.18 x 1.77 3.94 x 3.46 x 1.86 4.22 x 3.96 x 1.20	5.4 x 3.9 x 2.4 7.3 x 5.5 x 2.4	10.83 x 6.93 x 2.32	1.57 x 1.97 x 0.79 (40 mm x 50 mm x 20 mm)	<p>Similar.</p> <p>The dimensions of the proposed Stainless Steel Surgical Kits are within the range of the predicate and reference devices.</p>

Element	Proposed Device Stainless Steel Surgical Kits	Predicate Device Surgical and Prosthetic Trays (K220791)	Reference Device Washtrays (K231144)	Reference Device Biotech Dental Kits 2-piece metal trays (K212068)	Comparison
Raw materials	Lid, Base, Insert, and Bath: AISI 304L Holders: Colored Silicone	Base, Lid and Insert: PPSU polyphenylsulfone - Radel R-5000 Holders – Colored Silicone	<ul style="list-style-type: none"> • Metal Grid Base: Stainless steel 1.4301 • Metal grid base feet: Silicone • Large and small basket: Stainless steel 1.4303 • Lid with Handle: Stainless Steel 1.4310 • Silicone mat (inside the small basket): Colored Silicone • Instrument Holders (within the Overlay): PEEK, with Stainless steel springs • Overlay: Anodized aluminum alloy 	Base and Lid: Stainless Steel AISI 304L Holders: Medical grade silicone	Similar Same material as the predicate device for the silicone holders. Similar stainless steel materials as the reference devices.
Air permeance	Allows moist heat (steam) penetration to achieve sterilization	Allows moist heat (steam) penetration to achieve sterilization	Allows moist heat (steam) penetration to achieve sterilization	Allows moist heat (steam) penetration to achieve sterilization	Same
Maximum number of instruments	5 - 20 instruments	22 - 56 instruments	38 - 76 instruments	3 instruments	Similar and within range of the predicate and reference devices, combined. The maximum number of instruments that can be loaded in the proposed Stainless Steel Surgical Kits is lower than that of the predicate device (K220791).

Element	Proposed Device Stainless Steel Surgical Kits	Predicate Device Surgical and Prosthetic Trays (K220791)	Reference Device Washtrays (K231144)	Reference Device Biotech Dental Kits 2-piece metal trays (K212068)	Comparison
Mass of maximum load (g)	79.26– 318.77	271.9 - 563.5	1107.3	39.4	Similar and within the range of the predicate and reference devices, combined. The weight difference of the mass of maximum load of the proposed Stainless Steel Surgical Kits does not affect the sterilization process and sterility assurance level (SAL) of 10^{-6} as demonstrated by the sterilization validation.
Vent to Volume Ratio (in⁻¹)	0.15 – 10.18	0.033 – 0.046	2.54	0.9500 cm ² /cm ³ (2.413 in ⁻¹)	Similar or higher when compared to the predicate and reference devices. The difference in the vent to volume ratio (in ⁻¹) does not affect the sterilization process and sterility assurance level (SAL) of 10^{-6} as demonstrated by the sterilization validation.
Sterility	Provided non-sterile (to be steam sterilized by the end user)	Provided non-sterile (to be steam sterilized by the end user)	Provided non-sterile (to be steam sterilized by the end user)	Provided non-sterile (to be steam sterilized by the end user)	Same
Sterilization Method	Dynamic air removal (pre-vacuum)	Dynamic air removal (pre-vacuum)	Dynamic air removal (pre-vacuum)	Dynamic air removal (pre-vacuum)	Same
Sterilization Parameters	Dynamic air removal (pre-vacuum) at 132 °C (270	Dynamic air removal (pre-vacuum) at 132 °C (270	Dynamic air removal (pre-vacuum) at 132 °C (270	Dynamic air removal (pre-vacuum) at 132 °C (270	Same

Element	Proposed Device Stainless Steel Surgical Kits	Predicate Device Surgical and Prosthetic Trays (K220791)	Reference Device Washtrays (K231144)	Reference Device Biotech Dental Kits 2-piece metal trays (K212068)	Comparison
	°F) for 4 minutes with a 20 minute dry time.	°F) for 4 minutes with a 20 minute dry time.	°F) for 4 minutes with a 20 minute dry time.	°F) for 4 minutes with a 20 minute dry time.	
Sterile barrier	FDA cleared sterilization pouch (single pouch)	FDA cleared sterilization pouch (single pouch)	FDA cleared sterilization pouch (single pouch)	FDA cleared sterilization pouch (double pouch)	Same as the predicate and reference device (K231144).
Reusable	Yes	Yes	Yes	Yes	Same

7. Non-Clinical Performance Data

The proposed Stainless Steel Surgical Kits are reusable devices provided non-sterile which need to be end user cleaned and sterilized. Cleaning and sterilization of the proposed trays were validated according to the FDA guidance document, “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling”.

Non-clinical testing data submitted, referenced, or relied upon, including acceptance criteria and set specifications in test methodology and standards, are summarized below:

Test Name	Test Methodology	Purpose	Acceptance Criteria	Results
Cleaning (Manual Pre-Cleaning and Automated Cleaning) validation	ANSI/AAMI ST98:2022	To validate that the trays can be cleaned as specified on labeling	No visible soil. Residual protein: ≤ 6.4 µg/cm ² Total Organic Carbon: ≤ 12 µg/cm ²	Pass
Sterilization cycle validation and drying time validation	<ul style="list-style-type: none"> • ISO 17665:2024 • AAMI TIR 12:2020/(R) 2023 	<p>To validate that the trays can be sterilized via moist-heat sterilization as specified on labeling (132° C for 4 minutes)</p> <p>To validate that the drying time parameters are suitable</p>	<p>Sterility assurance level (SAL) of ≤ 10⁻⁶</p> <p>No visible moisture ≤ 1% weight gain of packaging and absorbable materials</p>	Pass
Service Life validation	<ul style="list-style-type: none"> • ANSI/AAMI ST98:2022 • Internal Test - visual and functional tests 	To confirm that the trays can withstand simulated use and up to 50 reprocessing cycles	<p>Internal visual and functional acceptance criteria must be met.</p> <p>Total Organic Carbon: ≤ 12 µg/cm²</p>	Pass
Transportation validation	<ul style="list-style-type: none"> • ASTM D4332-22 • ASTM D4169-23e1 • Internal Test – visual and functional tests 	To confirm that the packaging protects the device during simulated distribution	Internal visual and functional acceptance criteria must be met.	Pass
Cytotoxicity testing	ISO 10993-5:2009/(R)2022	<p>To confirm that no cytotoxic substances are released after 50 or 51 reprocessing cycles</p> <p>To confirm that no cytotoxic residuals of detergent remain on the device after 8 simulated use cycles</p>	Inhibition of cell proliferation must be at or below 30% compared to untreated cultures	Pass

8. Conclusion

The conclusions drawn from the non-clinical test data and evaluation support that the proposed Stainless Steel Surgical Kits are as safe, as effective and perform as well as the legally marketed predicate device Dentsply Sirona Surgical Trays (K220791).