December 23, 2025

Nakanishi, Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
7 Giralda Farms, Suite 120a
Madison, New Jersey 07940

Re: K254163
Trade/Device Name: VarioSurg 4
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone cutting instrument and accessories
Regulatory Class: Class II
Product Code: DZI, ELC
Dated: December 22, 2025
Received: December 22, 2025

Dear Dave Yungvirt:

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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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)* K251463

Device Name
VarioSurg 4

Indications for Use *(Describe)*
The VarioSurg 4 is intended for bone cutting in oral surgery, scaling and root planing, and retrograde preparation of root canals.

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

K254163

Submitter:	NAKANISHI INC. 700 Shimohinata Kanuma, Tochigi 322-8666 Japan
Contact Person:	Mr. Masaaki Kikuchi Corporate Vice President, Quality/Regulatory Affairs Division TEL: +81-289-64-7277 FAX: +81-289-62-9738 m-kikuchi@nsk-nakanishi.co.jp
Date Prepared:	December 22, 2025
Submission Type:	Traditional 510(k) Submission
Trade Name:	VarioSurg 4
Classification Name:	Bone cutting instrument and accessories.
Primary Classification:	DZI 872.4120 Drill, Bone, Powered
Subsequent Classifications:	ELC 872.4850 Scaler, Ultrasonic
Predicate Device:	VarioSurg Bone Surgery System and Ultrasonic Scaler 510(k) Number: K073678 Product Codes: DZI, ELC
Reference Devices:	MT-Bone 510(k) Number: K242432 Product Codes: DZI, ELC
Reference Devices:	Surgic Pro2 (Surgic Pro2 OPT), Surgic Pro2 (Surgic Pro2 NON-OPT) 510(k) Number: K233117 Product Codes: EBW
Device Description:	VarioSurg 4 consists of the control unit, the foot control, the ultrasonic handpiece, and accessories. The control unit generates an ultrasonic electrical signal and is used to control functions such as power output, irrigation flow, and operation mode. The foot control allows for "hands-free" control of the irrigation flow, program selection, and turning the ultrasound on/off. The ultrasonic handpiece (VS4-LED-HPSC) incorporates a piezoelectric transducer that converts the electrical signal into mechanical vibrations and is also equipped with LED illumination. VarioSurg 4 is intended for use in dental periodontal therapy and dental oral surgery for procedures such as bone cutting, root canal preparation, and the removal of deposits from teeth. The device is designed to be used with the ultrasonic handpiece, which drives various tips vibrating at an ultrasonic frequency to perform cutting, removal, and incision of hard and soft tissues within the oral cavity. A feature of this product is its Bluetooth connectivity with the foot control and its ability to connect to the Surgic Pro2 (K233117) system. When

connected, a single foot control can operate both systems.
The product is supplied non-sterile. The handpiece and tips are to be cleaned and sterilized at a medical facility before use and are intended for repeated use.

Indication for Use:

The VarioSurg 4 is intended for bone cutting in oral surgery, scaling and root planing, and retrograde preparation of root canals.

Summary of Technological Characteristics:

The VarioSurg 4 is an ultrasonic surgical system driven by an AC power source, which supplies power to and controls the functions of a compatible handpiece. Its operating principle is identical to that of the Predicate device (K073678), wherein an electrical signal from the generator is converted into mechanical vibrations by a piezo transducer, which in turn drives the attached tip (not included in this submission). This fundamental technology, as well as functions such as controlling ultrasonic output and irrigation volume, are shared with the Predicate device.

On the other hand, the subject device differs from the Predicate device in several aspects, including the dimensions and weight of the control unit, the adoption of a touch panel display, and the connection method for the wireless foot control. These modifications reflect user convenience and market strategy and do not alter the intended use or the fundamental scientific technology. It has been confirmed through compliance with relevant standards and comparison with the Reference device that these changes do not raise new questions of safety or effectiveness. Therefore, these minor differences do not affect the substantial equivalence of the device.

510(k) SUMMARY

Characteristics	Subject Device		Predicate Device	Reference Device 1	Reference Device 2	Comparison
Device Name	VarioSurg 4	VarioSurg 4	VarioSurg Bone Surgery System and Ultrasonic Scaler	MT-Bone	Surgic Pro2 (Surgic Pro2 OPT), Surgic Pro2 (Surgic Pro2 NON-OPT)	–
Model	VarioSurg 4 (120V)	VarioSurg 4 w/o FC (120V)	-	-	-	–
510(k) Submitter	NAKANISHI INC.	NAKANISHI INC.	NAKANISHI INC.	Mectron S.p.A.	NAKANISHI INC.	-
510(k) Number			K073678	K242432	K233117	-
Product Code	DZI, ELC	DZI, ELC	DZI, ELC	DZI, ELC	EBW	Same
Device Class	II	II	II	II	I	Same
Regulation Number	21 CFR 872.4120	21 CFR 872.4120	21 CFR 872.4120	21 CFR 872.4120	21 CFR 872.4200	Same
Operation principle	A sinusoidal electrical signal, at ultrasonic frequency (f > 20 kHz), is delivered by the generator. This signal is applied to the 'piezoelectric ceramic' located inside the transducer. Piezoelectric ceramic converts this signal into mechanical vibrations. These vibrations are at the same ultrasonic frequency as the electrical signal. The mechanical vibrations are propagated towards the distal end of the transducer. The "TIP" insert, which is attached at the distal	A sinusoidal electrical signal, at ultrasonic frequency (f > 20 kHz), is delivered by the generator. This signal is applied to the 'piezoelectric ceramic' located inside the transducer. Piezoelectric ceramic converts this signal into mechanical vibrations. These vibrations are at the same ultrasonic frequency as the electrical signal. The mechanical vibrations are propagated towards the distal end of the transducer. The "TIP" insert, which is attached at the distal end of the transducer, vibrates at	A sinusoidal electrical signal, at ultrasonic frequency, is delivered by the generator. This signal is applied to the piezoelectric ceramic located inside the transducer. Piezoelectric ceramic converts this signal into mechanical vibrations. These vibrations are at the same ultrasonic frequency as the electrical signal. The mechanical vibrations are propagated towards the distal end of the transducer. The insert, which is attached at the distal end of the transducer, vibrates at ultrasonic frequency	Piezoelectric ultrasonic technology generates mechanical micro-vibrations of the insert tips. The piezoelectric transducer uses piezoceramic disks to convert the generator's electrical signal into ultrasonic vibration of the insert tip.	Power is supplied to the control unit by operations on the foot control. This makes the motor run and the bur attached to the handpiece rotate.	Same: The subject device and predicate device convert an ultrasonic frequency electrical signal into mechanical vibrations using a piezoelectric ceramic, which then vibrates the tip at ultrasonic frequencies.

Characteristics	Subject Device		Predicate Device	Reference Device 1	Reference Device 2	Comparison
Device Name	VarioSurg 4	VarioSurg 4	VarioSurg Bone Surgery System and Ultrasonic Scaler	MT-Bone	Surgic Pro2 (Surgic Pro2 OPT), Surgic Pro2 (Surgic Pro2 NON-OPT)	–
Model	VarioSurg 4 (120V)	VarioSurg 4 w/o FC (120V)	-	-	-	–
	end of the transducer, vibrates at ultrasonic frequencies and makes it possible to achieve the aimed purpose.	ultrasonic frequencies and makes it possible to achieve the aimed purpose.	and makes it possible to achieve the aimed purpose.			
Indications for Use	The VarioSurg 4 is intended for bone cutting in oral surgery, scaling and root planing, and retrograde preparation of root canals.	The VarioSurg 4 is intended for bone cutting in oral surgery, scaling and root planing, and retrograde preparation of root canals.	The VarioSurg device is intended for bone cutting in oral surgery, scaling and root planing, and retrograde preparation of root canals.	MT-Bone is a piezoelectric ultrasonic device, consisting of handpieces and associated tip inserts, intended for: - Bone cutting, osteotomy, osteoplasty and drilling in a variety of oral surgical procedures, including implantology, periodontal surgery, surgical orthodontic and surgical endodontic procedures; - Scaling applications, including: Scaling: All general procedures for removal of supragingival and interdental calculus & plaque deposits; o Periodontology: Periodontal therapy and debridement for all types of periodontal diseases, including periodontal	The Surgic Pro2 is intended for use in dental oral surgery and dental implant. The main unit is designed to be used with a specific dental micromotor that drives dental handpieces fitted with appropriate tools to cut hard tissues in the mouth.	Similar: The subject device's Indications for Use are substantially the same as the predicate's. Wording differences merely provide greater specificity for procedures already encompassed by the predicate's broader indications. This is further supported by the reference device 1 whose indications explicitly include implantology and periodontal surgery, confirming these are established applications. Therefore, these descriptive clarifications do not

Characteristics	Subject Device		Predicate Device	Reference Device 1	Reference Device 2	Comparison
Device Name	VarioSurg 4	VarioSurg 4	VarioSurg Bone Surgery System and Ultrasonic Scaler	MT-Bone	Surgic Pro2 (Surgic Pro2 OPT), Surgic Pro2 (Surgic Pro2 NON-OPT)	–
Model	VarioSurg 4 (120V)	VarioSurg 4 w/o FC (120V)	-	-	-	–
				pocket irrigation and cleaning; o Endodontics: All treatments for root canal reaming, irrigation, revision, filling, gutta-percha condensation and retrograde preparation; o Restorative and Prosthetics: Cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations and inlay/onlay condensation.		alter the scope of use or raise new questions of safety and effectiveness.
Prescription / over-the counter use	Prescription	Prescription	Prescription	Prescription	Prescription	Same
Control Unit						
Power Supply	AC 120 V	AC 120 V	AC 120 V	AC 100 - 240 V	AC 120 V	Same: The power supply of the subject device and the predicate device are same.
Power Frequency	50 / 60 Hz	50 / 60 Hz	50 / 60 Hz	50 / 60 Hz	50 / 60 Hz	Same: The power frequency of the subject device and the predicate device are same.

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Characteristics	Subject Device		Predicate Device	Reference Device 1	Reference Device 2	Comparison
Device Name	VarioSurg 4	VarioSurg 4	VarioSurg Bone Surgery System and Ultrasonic Scaler	MT-Bone	Surgic Pro2 (Surgic Pro2 OPT), Surgic Pro2 (Surgic Pro2 NON-OPT)	–
Model	VarioSurg 4 (120V)	VarioSurg 4 w/o FC (120V)	-	-	-	–
Vibration Frequency	28 - 32 kHz	28 - 32 kHz	28 - 32 kHz	24 - 36 kHz	N/A	Same: The vibration frequency of the subject device and the predicate device are same.
Electrical Safety Class	BF type	BF type	BF type	B type	B type	Same: The Electrical Safety Class of the subject device and the predicate device are same.
Device Type	Table top device	Table top device	Table top device	Table top device	Table top device	Same: The device type Class of the subject device and the predicate device are same.
Dimension	245 x 235 x 90 mm	245 x 235 x 90 mm	268 x 230 x 103 mm	260 x 162 x 330 mm	245 x 235 x 90 mm	Different: It does not raise additional issues related to substantial equivalence because of the design of the control unit.
Weight	2.2 kg	2.2 kg	3.1 kg	4.7 kg	2.1 kg	
Accessories	Sterilization Cassette (VA-SG-CASE), Irrigation Tube (Pack of 5), Tube Holder (7 pcs.), Coolant Solution Hanger Post,	Sterilization Cassette (VA-SG-CASE), Irrigation Tube (Pack of 5), Tube Holder (7 pcs.), Coolant Solution Hanger Post,	Sterilization Cassette (VA-SG-CASE), Irrigation Tube (Pack of 5), Tube Holder (7 pcs.), Coolant Solution Hanger Post	Reusable inserts for bone surgery, Dynamometric wrench, Irrigation kit, Protective foils	Coolant Solution Hanger Post, Tube Holder (7 pcs.), Protection Plug, Calibration Bur,	Different: Some accessories (Wired Foot Control (FC-78), Link Stand3 (LS-3)) have been

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Characteristics	Subject Device		Predicate Device	Reference Device 1	Reference Device 2	Comparison
Device Name	VarioSurg 4	VarioSurg 4	VarioSurg Bone Surgery System and Ultrasonic Scaler	MT-Bone	Surgic Pro2 (Surgic Pro2 OPT), Surgic Pro2 (Surgic Pro2 NON-OPT)	–
Model	VarioSurg 4 (120V)	VarioSurg 4 w/o FC (120V)	-	-	-	–
	Wired Foot Control (FC-78), Link Stand3 (LS-3)	Wired Foot Control (FC-78), Link Stand3 (LS-3)			Y-Connector, Irrigation Tube (Pack of 5)	added. These reflect market strategy and user preferences and therefore do not have an impact on safety and efficacy.
Standards	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Same: The electrical safety standards of the subject device and the predicate device are same.
Foot Control Connectivity	Wireless or Wired	The model *VarioSurg 4 w/o FC (120V)* does not include Foor Control	Wired	Wired	Wireless	Different: The foot control connectivity of the subject device and the predicate device are different. However, since the connectivity method of the predicate device and Reference Device 2 is included, this supports substantial equivalence.
Display operation method	Touch panel type	Touch panel type	Button type	Touch panel type	Touch panel type	Different: The display operation method of the subject device and the predicate device are different. However,

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Model	VarioSurg 4 (120V)	VarioSurg 4 w/o FC (120V)	-	-	-	–
						they are same to the display operation method of the reference device 1, supporting substantial equivalence.
Vibration mode	PERIO mode ENDO mode SURG mode (BURST mode)	PERIO mode ENDO mode SURG mode (BURST mode)	PERIO mode ENDO mode SURG mode (BURST mode)	PIEZOSURGERY channel PIEZODRILL channel	N/A	Same: The display operation method of the subject device and the predicate device are same.
Foot Control						
Model	FC-86	The model *VarioSurg 4 w/o FC (120V)* does not include Foor Control	FC-51	FS-06	FC-81	-
Dimension	260 x 185 x 65 mm	N/A	249 x 168 x 103 mm	Unknown	260 x 200 x 155 mm	Different: It does not raise additional issues related to substantial equivalence because of the design of the foot control.

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Characteristics	Subject Device		Predicate Device	Reference Device 1	Reference Device 2	Comparison
Device Name	VarioSurg 4	VarioSurg 4	VarioSurg Bone Surgery System and Ultrasonic Scaler	MT-Bone	Surgic Pro2 (Surgic Pro2 OPT), Surgic Pro2 (Surgic Pro2 NON-OPT)	–
Model	VarioSurg 4 (120V)	VarioSurg 4 w/o FC (120V)	-	-	-	–
Wireless Connection Method of Foot Control	Bluetooth	N/A	N/A (Wired)	N/A (Wired)	Bluetooth	Different: The wireless connection method of Foot Control of the subject and the predicate device are different. However, they are same to the wireless connection method of foot control of the reference device 2, supporting substantial equivalence.
Foot Control Degree of Protection	IPX8	N/A	IPX8	IPX8	IPX8	Same: The foot control degree of protection of the subject device and the predicate device are same.
Ultrasonic Handpiece						
Model	VS4-LUX-HPSC	VS4-LUX-HPSC	VS-LED-HPSC	PIEZOSURGERY MT PIEZODRILL MT		-
Vibration Frequency	28 - 32 kHz	28 - 32 kHz	28 - 32 kHz	24 – 36 kHz		Same: The vibration frequency of the subject device and the predicate device are same.

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Characteristics		Subject Device		Predicate Device	Reference Device 1	Reference Device 2	Comparison
Device Name		VarioSurg 4	VarioSurg 4	VarioSurg Bone Surgery System and Ultrasonic Scaler	MT-Bone	Surgic Pro2 (Surgic Pro2 OPT), Surgic Pro2 (Surgic Pro2 NON-OPT)	–
Model		VarioSurg 4 (120V)	VarioSurg 4 w/o FC (120V)	-	-	-	–
Water Flow Volume		10 - 76 mL / min	10 - 76 mL / min	9 - 90 mL / min	0 - 75 mL / min		Similar: The maximum water flow volume of the subject device falls within the range of that of the predicate device.
Light source		White LED	White LED	White LED	White LED		Same: The light source of the subject device and the predicate device are same.
Dimension		φ20.4 x 129.3 mm	φ20.4 x 129.3 mm	φ21.5 x 123.6 mm	Unknown		Different : It does not raise additional issues related to substantial equivalence because of the design of the ultrasonic handpiece.
Weight		171 g	171 g	210.8 g	Unknown		
Patient Contacting Materials	**Direct**	Multicomponent glass, PEI, Stainless steel	Multicomponent glass, PEI, Stainless steel	Unknown	Unknown		Different : Conformity to ISO 10993-1 supports substantial equivalence.
	Indirect	Waterlines	Waterlines	Waterline	Unknown		

510(k) SUMMARY

Characteristics	Subject Device		Predicate Device	Reference Device 1	Reference Device 2	Comparison
Device Name	VarioSurg 4	VarioSurg 4	VarioSurg Bone Surgery System and Ultrasonic Scaler	MT-Bone	Surgic Pro2 (Surgic Pro2 OPT), Surgic Pro2 (Surgic Pro2 NON-OPT)	–
Model	VarioSurg 4 (120V)	VarioSurg 4 w/o FC (120V)	-	-	-	–
Sterilization	Pre-Vacuum (Dynamic Air Removal): 132°C, 4 min Gravity Displacement: 132°C,15 min	Pre-Vacuum (Dynamic Air Removal): 132°C, 4 min Gravity Displacement: 132°C,15 min	Pre-Vacuum (Dynamic Air Removal): 132°C, 4 min or 135°C, 3 min Gravity Displacement: 132°C,15 min or 135°C, 10 min	Unknown		Same: Sterilization Conditions of the subject device and the predicate device are same.
Connectable Tip	H-SG1, SG3, SG5, SG6D, SG7D, SG11 etc.	H-SG1, SG3, SG5, SG6D, SG7D, SG11 etc.	H-SG1, SG3, SG5, SG6D, SG7D, SG11 etc.	Unknown		Same: The tips compatible with both the subject device and the predicate device are identical.
Accessories	Handpiece Stand, Tips Holder, Tip Wrench (CR-30), E Tip Wrench, VS Tip Wrench (CR-40)	Handpiece Stand, Tips Holder, Tip Wrench (CR-30), E Tip Wrench, VS Tip Wrench (CR-40)	Handpiece Stand, Tips Holder, Tip Wrench (CR-30), E Tip Replacement Wrench	Unknown		Same: The VS Tip Wrench (CR-40) has been added. This reflects market strategy and user preferences, and therefore does not impact safety or efficacy.

The Operation Manuals provide detailed instructions and information for safe and effective use of the device and users are expected to adhere to the instructions and other information. Before using the product, be sure to read the manual thoroughly in order to utilize it more effectively.

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Performance Test: The subject instrument was subjected to verification and validation testing for powered scaler performance, reprocessing, software, electrical safety, EMC, and cybersecurity to support substantial equivalence. The results of these tests demonstrate compliance with the requirements of the following standards and guidance.

- ISO 18397:2016 "Dentistry - Powered scaler "
- ISO 17664-1:2021 "Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices"
- ISO 17665-1:2006 "Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices"
- IEC 62304:2006+AMD1:2015 "Medical device software - Software life cycle processes"
- IEC 60601-1:2005+AMD1:2012+AMD2:2020 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"
- IEC 60601-1-2:2014+AMD1:2020 "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests"
- IEC 81001-5-1:2021 "Health software and health IT systems Safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle"
- FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"
- FDA guidance document "Content of Premarket Submissions for Device Software Functions"
- FDA guidance document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"

Biocompatibility Test: Based on its Indications for Use, the subject device, the ultrasonic handpiece, is classified as a device that has limited contact (less than 24 hours) with externally communicating medical devices and tissue / bone / dentin. To support substantial equivalence, biocompatibility testing was conducted using the device with similar materials and design. The test results demonstrate compliance with the requirements of the following standards and guidance:

- ISO 10993-1:2018 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
- FDA guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process""

510(k) SUMMARY

Technological Comparison

The subject device has some differences in technical characteristics from those of the predicate and reference devices. These differences are limited to minor variations in basic shape and structure and do not impact the safety, effectiveness, or substantial equivalence of the subject device as confirmed by the evaluation performed.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Non-clinical bench performance testing was conducted on the subject device to support its safety and effectiveness. The verification demonstrates that the subject device is as safe and effective as the predicate device and performs as intended under the specified use conditions.

Based on the similarities in intended use, principles of operation, functional design, and non-clinical bench performance testing data, the subject device is substantially equivalent to the predicate device listed above.