December 21, 2021

KaVo Dental GmbH
Kerstin Henseler
Regulatory Affairs Manager
Bismarckring 39
Biberach, 88400
GERMANY

Re: K213139
Trade/Device Name: SURGmatic S15 L Pro
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EGS
Dated: September 24, 2021
Received: September 27, 2021

Dear Kerstin Henseler:

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, 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)*
K213139

Device Name
SURGmatic S15 L Pro

Indications for Use *(Describe)*
The SURGmatic S15 L Pro handpiece is intended for:
- Oral, jaw and facial surgery
- Tooth extraction procedures
- Root resection
- Osteotomy
- Removal of carious material
- Tooth, cavity and crown preparations
- Processing of fillings

The SURGmatic S15 L Pro is for use by a trained professional in the field of general dentistry and/or oral surgery.

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 K213139

SURGmatic S15 L Pro handpiece

1. Submitter Information:

KaVo Dental GmbH
Bismarckring 39
88400 Biberach, Germany

Contact Person: Kerstin Henseler
E-Mail: kerstin.henseler@kavo.com
Telephone Number: (+49) 7351-56-2431

Date Prepared: September 24, 2021

2. Device Name:

- Proprietary Name: SURGmatic S15 L Pro
- Manufacturer: KaVo Dental GmbH
- Common Name: Dental handpiece, Contra-Angle Attachment
- Classification Name: Dental Handpiece and Accessories
- CFR Number: 21 CFR §872.4200
- Device Class: 1
- Product Code: EGS

3. Predicate Device:

Predicate Device (Primary):

- Proprietary Name: SURGmatic (K140308)
- Manufacturer: KaVo Dental GmbH
- Common Name: Dental Handpiece, Contra-Angle Attachment
- Classification Name: Dental Handpiece and Accessories
- CFR Number: 872.4200
- Device Class: I
- Product Code: EBW, EGS

Reference Device:

- Proprietary Name: SUPERtorque, GENTLEpower Handpieces (K073478)
- Manufacturer: KaVo Dental GmbH
- Common Name: Dental Handpiece, Air-Powered
- Classification Name: Dental Handpiece and Accessories
- CFR Number: 872.4200
- Device Class: I
- Product Code: EFB

4. Description of Device:

The electrical-driven SURGmatic S15 L Pro handpieces are dental handpieces in accordance with 21 CFR § 872.4200 (dental handpieces and accessories) designed for use by a trained professional in the field of general dentistry only. The device is an electrically driven handpiece that is reusable and provided with a fiber optic light system. The electrical motor includes the light source and the SURGmatic S15 L Pro handpiece is provided with a fiber optic light transmitter to transport the light to the bur side. DIN EN ISO 14457 regulates the minimum illuminance. The dental handpieces can be sterilized in a steam sterilizer (autoclave). SURGmatic handpieces equipped with a handpiece connector in accordance with ISO 3964 are connected to a treatment unit by means of a hose and the electrical motor and receive the energy for the gear, cooling water and air for conservative dental treatment as well as the light for illumination of the operation area through corresponding output openings. Burs in accordance with ISO 1797-1 must be used with the SURGmatic handpieces. Based on the INTRAmatic connection that meets the ISO 3964 standard, the SURGmatic handpieces fit with any electrical dental motor which is produced in accordance to this standard. The SURGmatic handpieces interact with the patient through a rotating bur with the patient teeth according to the intended use.

The electrical motor rotates with an idle speed of 40.000 1/min and the gear ratio of the SURGmatic S15 L Pro instrument amounts to 1:5 (exactly 1:4,71).

The bur is held in the rotating head drive with the help of a collet and can be released by a push-button mechanism. DIN EN ISO 14457 regulates the minimum extraction force of the bur.

Principle of Operation / Mechanism of Action:

Rotatory movement. Surgical instruments for the mouth, jaw and facial surgery are straight and contra-angle handpieces which are powered by electrical surgical motors. Electrical energy is converted into mechanical energy through the motor. This mechanical energy is transferred to the drive trains in the contra-angle handpiece in the form of a rotary movement via a coupling interface in accordance with DIN EN ISO 3964. The force is transmitted through shafts and gear components to another coupling interface located in the head housing, which is designed for safe insertion and removal of tools in accordance with DIN EN ISO 1797. The mechanical energy is passed on to the cutting part of these tools and thus to the treatment site by this interface.

5. Indications for Use:

The SURGmatic S15 L Pro handpiece is intended for:
- Oral, jaw and facial surgery
- Tooth extraction procedures
- Root resection
- Osteotomy
- Removal of carious material
- Tooth, cavity and crown preparations
- Processing of fillings

The SURGmatic S15 L Pro is for use by a trained professional in the field of general dentistry and/or oral surgery.

6. Description of Substantial Equivalence:

Details of the similarities between subject and predicate device:

The similarities between the subject and predicate device is mainly the indications for use and the intended use with the only difference being choice of similar wording. It can be said that the handpieces are for use in the field of general dentistry and/or oral surgery. Furthermore, equally similar is the drive by a motor, which drives trains in the contra-angle handpiece in the form of a rotary movement via a coupling interface in accordance with DIN EN ISO 3964. The force is transmitted through shafts and gear components to another coupling interface located in the head housing. Technical Specifications like light illumination, type of chuck, power source, dental bur, speed range, light intensity are the same. To maintain the handpiece the same automated handpiece lubricant system and lubricant are used. The SURGmatic S15 L Pro handpiece has the same type of chuck as the both predicate devices which is push button.

Furthermore, the proposed device and the predicate devices complies with performance standards ISO 14457; Dentistry - Handpieces and motors as well as Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system).

Details of the differences between subject and predicate device:

There are no major differences however there are a few minor differences such as the course of air and water ports, direct and indirect patient-contacting materials and dimensions. The SURGmatic S15 L Pro handpiece is available with External spray which is transferred internally into the spray insert. The other handpieces have an external or internal spray instead. For all handpieces the material stainless steel is used and is used for nearly all direct and indirect patient-contacting parts with the only difference by identifying now also the pad printing ink & the glass rod fiber as a direct / indirect patient-contacting part. The dimensions differ in a few millimeters.

Conclusion:

Based on a comparison of intended use, indications for use, technological characteristics, principle of operation, features, and performance data, the SURGmatic S15 L Pro handpiece 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.

Device Comparison Table:

Table 5.1

Descriptive Information	**Subject Device SURGmatic S15 L Pro**	**Primary Predicate Device SURGmatic (K140308)**	**Reference Device SUPERtorque, GENTLEpower Handpieces and Attachement (K073478)**	**Comparison**
Manufacturer	KaVo Dental GmbH	KaVo Dental GmbH	KaVo Dental GmbH	Same

Pictorial Representation				N/A
Regulatory Classification				
Regulation #	21 CFR §872.4200	21 CFR §872.4200	21 CFR §872.4200	Same
Regulation Title	Dental Handpiece and Accessories	Dental Handpiece and Accessories	Dental Handpiece and Accessories	Same
Regulation Class	Class I	Class I	Class I	Same
Product Code	EGS	EBW / EGS	EFB	Similar to Primary Predicate
Indications for Use / Intended Use				
Indications for Use	The SURGmatic S15 L Pro handpiece is intended for: - Oral, jaw and facial surgery - Tooth extraction procedures - Root resection - Osteotomy - Removal of carious material - Tooth, cavity and crown preparations - Processing of fillings The SURGmatic S15 L Pro is for use by a trained professional in the field of general dentistry and/or oral surgery.	The medical device is intended for the following uses: Surgery such as setting an implant, bone augmentation, sinus lift, tooth extraction procedures, implantology, osteotomia, root resection and oral, jaw and facial surgery.	The GENTLEpower Handpieces and Attachments are intended for the removal of carious material, excess filling material, reducing hard tooth structure, cavity and crown preparation, root canal preparation, finishing tooth preparations, restorations and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.	Same as Primary Predicate and Reference Device with the only difference being choice of similar wording.
Intended Use	The electrical-driven SURGmatic S15 L Pro handpiece is a dental handpiece in accordance with 21 CFR § 872.4200 (dental handpieces and accessories) designed for use by a trained professional in the field of general dentistry only.	The electrical-driven SURGmatic handpieces are dental handpieces in accordance with 21 CFR § 872.4200 (dental handpieces and accessories) and is only intended for dental treatment.	The GENTLEpower Handpieces and Attachments are dental instruments for use by a trained professional in general dentistry. The handpieces and attachments are powered by either an air-motor or electric motor.	Same
Device Design				
Principles of Operation	Electrical energy is converted into mechanical energy through the motor. This mechanical energy is transferred to the drive trains in the contra-angle handpiece in the form of a rotary movement via a coupling interface in accordance with DIN EN ISO 3964. The force is transmitted through shafts and gear components to another coupling interface located in	Through the micro motor connected to the dental treatment unit the contra-angle handpieces equipped with a handpiece connection according to ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982) receives the energy, the cooling water and air for treatment and	Through the micro motor connected to the dental treatment unit the contra-angle handpieces equipped with a handpiece connection according to ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982) receives the energy, the cooling water and air for	Similar to Primary Predicate and Reference Device

	the head housing, which is designed for safe insertion and removal of tools in accordance with DIN EN ISO 1797. The mechanical energy is passed on to the cutting part of these tools and thus to the treatment site by this interface.	the light for illumination the operating area.	treatment and the light for illumination the operating area.	
Air / water ports	External spray which is transferred internally into the spray insert	External Spray	Internal Spray	Similar to Primary Predicate and Reference Device
Composition of Materials				
Direct / Indirect patient-contacting materials	Stainless Steel Pad printing ink Glass Rod Fiber	Stainless Steel	Stainless Steel	Similar to Primary Predicate and Reference Device
Technical Specifications				
Light illumination	Fibreoptic	Fibreoptic	Fibreoptic	Same
Dimension	Headsize-High: 14.7mm Headsize-Diameter: 10.2mm Handpiece length: 97.5mm	Headsize-High: 13.8mm Headsize-Diameter: 9.8mm Handpiece length: 96.5mm	Headsize-Height: 24mm Headsize-Diameter: 10.5mm Handpiece length: 80-100mm	Similar to Primary Predicate and Reference Device
Type of chuck	Push Button	Push Button, lever chuck	Push Button	Same as Reference Device
Power Source	Electric Motor	Electric Motor	Electric Motor	Same
Dental Bur	Burs in accordance with ISO 1797-1 can be used	Burs in accordance with ISO 1797-1 can be used	Burs in accordance with ISO 1797-1 can be used	Same
Speed Range	Up to 40,000 rpm	Up to 40,000 rpm	High-speed: Approx. 200,000 rpm Low-speed: 100 – 40,000 rpm	Same as Primary Predicate
Light Intensity	Approx. 25,000 Lux	Approx. 25,000 Lux	Approx. 25,000 Lux	Same
Lubricant				
Automated handpiece Lubricant system	KaVo QUATTROcare (K071288)	KaVo QUATTROcare (K071288)	KaVo QUATTROcare (K071288)	Same
Lubricant	KaVo Spray America QUATTROcare Plus Spray America (K071288)	KaVo Spray America QUATTROcare Plus Spray America (K071288)	KaVo Spray America QUATTROcare Plus Spray America (K071288)	Same
Performance Testing				
Complies to Standards	Complies with: ISO 14457 (Dentistry - Handpieces and motors)	Complies with: ISO 14457 (Dentistry - Handpieces and motors)	Complies with: ISO 7785-2 (Dental handpieces - Part 2:	Same

	ISO 1797 (Dentistry - Shanks for rotary and oscillating instruments) ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors)	ISO 1797-1 (Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals) ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors)	Straight and geared angle handpieces) ISO 1797 (Dentistry - Shanks for rotary instruments) ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors)	
Sterilization	Sterilizable according to ISO 17665-1 (Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices on the final, finished device	Sterilizable according to ISO 17665-1 (Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices on the final, finished device	Sterilizable according to ISO 17665-1 (Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices on the final, finished device	Same
Biocompatibility	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system).	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system).	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system).	Same

Non-Clinical Test Data:

Performance bench testing according to international standards for Dental Handpieces has been conducted to determine conformance in regards to:

- Biocompatibility has been completed for the applicable components.
- Comparative performance testing of the functions of the Proposed device compared to the cleared stand-a-lone device.

Furthermore, the performance of the SURGmatic S15 L Pro has been verified utilizing the following standards:

- ISO 10993-1:2018: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5:2009: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2010: Biological evaluation of medical devices -Part 10: Tests for irritation and skin sensitization.
- ISO 7405:2018 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry.
- ISO 14971:2007: Medical devices - Application of risk management to medical devices.
- IEC 62366-1:2015-02: Medical devices – Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
- ISO 17664:2017: Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices.
- ISO 14457:2017: Dentistry - Handpieces and motors

- AAMI / ANSI ST79:2017: Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ISO 3964:2016: Dentistry - Coupling dimensions for handpiece connectors
- ISO 1797:2017: Dentistry - Shanks for rotary and oscillating instruments
- 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 on the final, finished device

Clinical Performance Data:

Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterize all performance aspects of the device based on well-established scientific and engineering principles. Clinical testing has not been conducted on this product.

Conclusion as to Substantial Equivalence:

Based on a comparison of intended use, indications, technological characteristics, principle of operation, and performance data, the SURGmatic S15 L Pro is deemed to be substantially equivalent to the predicate device.