U.S. FOOD & DRUG ADMINISTRATION

September 19, 2024

DentalEZ, Inc., StarDental Division
Kay Engle
Regulatory Affairs Manager
1816 Colonial Village Lane
Lancaster, Pennsylvania 17601

Re: K240183
Trade/Device Name: Star E900 Handpiece Series
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EGS
Dated: August 21, 2024
Received: August 21, 2024

Dear Kay Engle:

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., RAC, CQIA
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240183

Device Name

Star E900 Handpiece Series

Indications for Use *(Describe)*

The Star E900 Handpiece Series are intended to be used for general dentistry by trained dental professionals. The intended use of the respective handpieces is dependent on the gear ratio.

Star E900 1:5 Handpiece: the removal of decayed matter, cavity and crown preparations, the removal of fillings and surface finishing of tooth and restoration surfaces.

Star E900 1:1 Handpiece: Cavity preparations, caries excavation, endodontic applications, processing of tooth and restoration surfaces.

Star E900 5:1 Handpiece: Cavity preparations, caries excavation, endodontic applications, processing of tooth and restoration surfaces.

Star E900 1:1 Straight Handpiece: prophylaxis treatment, crown preparations, polishing, finishing of tooth and restoration surfaces

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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I. SUBMITTER

DentalEZ Inc., StarDental Division
1816 Colonial Village Lane
Lancaster, PA 17601
Phone: (717) 291-1161
Contact Person:
Robert Young, Vice President of Research and Development
Kay Engle, Regulatory Affairs Manager

September 17, 2024

II. DEVICE

Trade Name: Star E900 Handpiece Series
Common Name: Handpiece, Contra- and Right-Angle Attachment, Dental
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I
Product Code: EGS

III. PREDICATE DEVICE

Clearance: K132356 dated January 31, 2014
Manufacturer: SciCan GmbH
Trade/Device Name: Sanao Dental Handpiece
Common Name: Handpiece, Contra- and Right-Angle Attachment, Dental
Regulation Number: 21CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulation Class: Class I
Product Code: EGS

IV. REFERENCE DEVICE

Clearance: K192412 dated January 6, 2020
Manufacturer: DentalEZ, Inc., StarDental Division
Trade/Device Name: SD500 High Speed Handpiece Series
Common Name: High Speed Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpieces and Accessories
Regulation Class: Class I
Product Code: EFB

V. DEVICE DESCRIPTION:

The Star E900 Handpiece Series are reusable contra-angle handpieces, driven by an ISO 3964 compliant electric micro-motor or air driven motor, that are intended for use by trained dental professionals in the field of general dentistry. The Star E900 1:5, 1:1 and 5:1 handpieces are designed for general applications to prepare dental cavities for restoration. The Star E900 1:1 Straight Handpiece is designed for prophylaxis treatment, crown preparations, polishing, finishing of tooth and restoration surfaces.

The Star E900 Handpiece Series feature an ISO 3964 compliant handpiece coupling connecting them to an electric micro-motor controlled by an electric control unit or air driven motor connected to a dental delivery unit. The control unit or delivery unit supplies energy to the handpiece which powers the gears within the handpieces. Depending on the applications, the handpieces have a maximum drive speed of 8,000 to 200,000 RPM's.

These handpieces are ergonomically shaped and have glass rod fiberoptics to illuminate the oral cavity during procedures. In addition, the handpieces have multi-port water spray. The exception to the fiber optics and water spray features is the Star E900 1:1 Straight Handpiece. This handpiece does not contain any fiberoptics nor does it have water spray capabilities.

All the handpieces in the Star E900 Handpiece series are composed of stainless steel and PEEK. They can be autoclaved.

The Star E900 Handpieces use only burs with hardened, tempered steel shanks or carbide shanks which are ISO 1797 compliant.

All handpieces in this series incorporate RFID (radio frequency identification) technology. This passive RFID tag does not have a built-in energy source. The RFID tag will allow the practitioner to track the device within the office only if the practitioner has a separate reader. The RFID reader will enable the practitioner to track such things as usage and maintenance.

The handpieces, with the exception of the Star E900 1:1 Straight Handpiece, incorporate a temperature sensor to be used in the service of the device, by trained service personnel, to access excessive heat in the handpiece, indicative of mechanical failure. This feature is not accessible to the practitioner.

VI. INDICATIONS FOR USE

Star E900 Handpiece Series are intended to be used for general dentistry work by a trained dental professional. The intended use of the respective handpieces is dependent on the gear ratio.

Star E900 1:5 Handpiece: the removal of decayed matter, cavity and crown preparations, the removal of fillings and surface finishing of tooth and restoration surfaces.

Star E900 1:1 Handpiece : Cavity preparations, caries excavation, endodontic applications, processing of tooth and restoration surfaces.

Star E900 5:1 Handpiece: Cavity preparations, caries excavation, endodontic applications,

processing of tooth and restoration surfaces.

Star E900 1:1 Straight Handpiece: prophylaxis treatment, crown preparations, polishing, finishing of tooth and restoration surfaces

VII. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The Star E900 Handpiece Series, the predicate device and the reference predicate devices have the same technological characteristics:

- Intended use
- Power source
- Use of the same base materials
- Autoclavable
- RFID technology

The following technological difference exist between the Star E900 Handpiece Series and the predicate devices:

- Temperature sensor

The Star E900 Handpiece Series are similar in design, function and intended use to other dental handpieces currently distributed in the U.S.

The technological differences noted do not affect the performance of the device.

The following tables summarize the comparison between the different Star E900 Handpiece in the series to the predicate devices.

Device	**Proposed device:**	**Predicate:**	**Reference Predicate:**
	Star E900 1:5 Handpiece	SANAO 200L (K132356)	SD500 High Speed Handpieces (K192412)
Indications for Use	This medical device is: - Intended to be used for general dentistry by trained dental professionals - Intended for the following applications: The removal of decayed matter, cavity and crown preparations, the removal of fillings and surface finishing of tooth and restoration surfaces.	This medical device is: - Intended for dental treatments only - Suggested for the following applications: The removal of decayed matter, cavity and crown preparations, the removal of fillings and surface finishing of tooth and restoration surfaces.	The SD500 High Speed Handpiece Series is used by trained dental professionals for a variety of procedures including but not limited to caries and amalgam removal, restorative work and crown preparations
Design	Contra-angle	Contra-angle	NA

Ratio	1:5	1:5	NA
Identification	Red ring	Red dot	NA
Operational Mode	Electric micro-motor or air driven	Electric micro-motor or air driven	Air driven
Type of chuck	Pushbutton autochuck	Pushbutton	Autochuck
Operating Pressure	36-72 PSI	39.2 PSI	38-43 PSI
Coupling Type	ISO 3964, Type 3, short	ISO 3964	ISO 9168,Type 3,Type 2

Device	**Proposed device:**	**Predicate:**	**Reference Predicate:**
Air/water ports	3 ports	3 ports	3 ports
Cooling	Water/air	Water/air	Water/air
Spray	Yes	Yes	Yes
Light	Yes – fiber optic glass rod	Yes – fiber optic glass rod	Yes – fiber optic glass rod
Bur Dimension	ISO 1797, Type 3	ISO 1797, Type 3	ISO 1797-1, Type 2
Max drive speed	40,000 rpm	40,000 rpm	NA
Maximum rotation speed	200,000 rpm	200,000 rpm	408,000 rpm
Material composition	Stainless steel PEEK	Stainless steel covered with Chrome, PEEK	Stainless steel PEEK
Lubricant	Electric Handpiece Lubricant (K163483)	StatCare (K062418)	NA
Sterility	Not supplied sterile – can be autoclaved	Not supplied sterile – can be autoclaved	Not supplied sterile – can be autoclaved
RFID technology	Yes – passive	No	Yes – passive
Thermal sensor	Yes – service use only	No	No

Device	Proposed device:	Predicate:	Reference Predicate:
	Star E900 1:1 Handpiece	SANAO 40L (K132356)	SD500 High Speed Handpieces (K192412)
Indications for Use	This medical device is: - Intended to be used for general dentistry by trained dental professionals - Intended for the following applications: Cavity preparation, caries excavation, endodontics applications, processing of tooth and restoration surfaces	This medical device is: - Intended for dental treatments only - Suggested for the following applications: Preparation of cavities, caries excavation, endodontic applications, processing of tooth and restoration surfaces	The SD500 High Speed Handpiece Series is used by trained dental professionals for a variety of procedures including but not limited to caries and amalgam removal, restorative work and crown preparations
Design	Contra-angle	Contra-angle	NA
Ratio	1:1	1:1	NA
Identification	Blue ring	Blue dot	NA

Device	Proposed device:	Predicate:	Reference Predicate:
Operational Mode	Electric micro-motor or air driven	Electric micro-motor or air driven	Air driven
Type of chuck	Pushbutton auto latch	Pushbutton auto latch	Autochuck
Operating Pressure	36-72 PSI	39.2 PSI	38-43 PSI
Coupling Type	ISO 3964, Type 3, short	ISO 3964	ISO 9168,Type 3,Type 2
Cooling	Water/air	Water/air	3 ports
Air/water ports	3 ports	1 port	Water/air
Spray	Yes	Yes	Yes
Light	Yes – fiber optic glass rod	Yes – fiber optic glass rod	Yes – fiber optic glass rod
Bur dimension	ISO 1797, Type 1	ISO 1797, Type 1	ISO 1797-1, Type 2
Max drive speed	40,000 rpm	40,000 rpm	NA
Maximum rotation speed	40,000 rpm	40,000 rpm	408,000 rpm
Material composition	Stainless steel PEEK	Stainless steel covered with Chrome, PEEK	Stainless steel PEEK
Lubricant	Electric Handpiece Lubricant (K163483)	StatCare (K062418)	NA
Sterility	Not supplied sterile – can be autoclaved	Not supplied sterile – can be autoclaved	Not supplied sterile – can be autoclaved
RFID	Yes – passive	No	Yes – passive
Thermal sensor	Yes – service use only	No	No

Device	Proposed device:	Predicate:	Reference Predicate:
	Star E900 5:1 Handpiece	SANAO 10L (K132356)	SD500 High Speed Handpieces (K192412)
Indications for Use	This medical device is: - Intended to be used for general dentistry by trained dental professionals - Intended for the following applications: Cavity preparation, caries excavation, endodontics applications, processing of tooth and restoration surfaces	This medical device is: - Intended for dental treatments only - Suggested for the following applications: Preparation of cavities, caries excavation, endodontic applications, processing of tooth and restoration surfaces	The SD500 High Speed Handpiece Series is used by trained dental professionals for a variety of procedures including but not limited to caries and amalgam removal, restorative work and crown preparations
Design	Contra-angle	Contra-angle	NA
Ratio	5:1	5:1	NA
Identification	Green ring	Green dot	NA
Operational Mode	Electric micro-motor or air driven	Electric micro-motor or air driven	Air driven
Type of chuck	Pushbutton auto latch	Pushbutton auto latch	Autochuck
Operating Pressure	36-72 PSI	39.2 PSI	38-43 PSI
Coupling Type	ISO 3964 Type 3, short	ISO 3964	ISO 9168,Type 3,Type 2
Air/water ports	3 ports	1 port	3 ports
Cooling	Water/air	Water/air	Water/air
Spray	Yes	Yes	Yes
Light	Yes – fiber optic glass rod	Yes – fiber optic glass rod	Yes – fiber optic glass rod
Bur Dimension	ISO 1797, Type 1	ISO 1797, Type 1	ISO 1797-1, Type 2
Max drive speed	40,000 rpm	40,000 rpm	NA
Maximum rotation speed	8,000 rpm	8,000 rpm	408,000 rpm
Material composition	Stainless steel PEEK	Stainless steel covered with Chrome, PEEK	Stainless steel PEEK
Lubricant	Electric Handpiece Lubricant (K163483)	StatCare (K062418)	NA

Sterility	Not supplied sterile – can be autoclaved	Not supplied sterile – can be autoclaved	Not supplied sterile – can be autoclaved
RFID Technology	Yes – passive	No	Yes – passive
Thermal sensor	Yes – service use only	No	No

Device	**Proposed device:**	**Predicate:**	**Reference Predicate**
	Star E900 1:1 Straight Handpiece	SANAO 40 ST (K132356)	SANAO PSO (K132356)
Indications for Use	This medical device is: - Intended to be used for general dentistry by trained dental professionals - Intended for the following applications: Prophylaxis treatment, crown preparation, polishing, finishing of tooth and restoration surfaces	This medical device is: - Intended for dental treatments only - Suggested for the following applications: Removal of carious material, cavities and crown preparations, removal of fillings, processing of tooth and restoration surfaces	This medical device is: - Only intended for dental treatment - Suggested for the following application: Prophylaxis treatment
Design	Straight Handpiece	Straight Handpiece	Contra-Angle
Ratio	1:1	1:1	5:1
Identification	Blue ring	Blue dot	Green dot
Operational Mode	Electric micro-motor or air driven	Electric micro-motor or air driven	Electric micro-motor or air driven
Type of chuck	Manual chuck	Manual chuck	NA
Operating Pressure	36-72 PSI	39.2 PSI	NA
Coupling Type	ISO 3964, Type 1, short	ISO 3964	ISO 3964
Air/water ports	None	1 port	None
Cooling	None	Water/air	None
Spray	None	Yes	None
Light	No	No	No
Bur Dimension	ISO 1797, Type 2	ISO 1797, Type 2	Mandrels with snap-on-function ISO 13295, Type 5
Max drive speed	40,000 rpm	40,000 rpm	8,000 rpm

Maximum rotation speed	40,000 rpm	40,000 rpm	40,000 rpm
Material composition	Stainless steel PEEK	Stainless steel covered with Chrome, PEEK	Stainless steel covered with Chrome
Lubricant	Electric Handpiece Lubricant (K163483)	StatCare (K062418)	StatCare (K062418)
Sterility	Not supplied sterile – can be autoclaved.	Not supplied sterile – can be autoclaved.	Not supplied sterile – can be autoclaved.
RFID	Yes – passive	No	No

VIII. PERFORMANCE DATA

The bench tests per the following standards were conducted to evaluate the functional performance and safety of the Star E900 Handpiece Series:

- ISO 14457: 2017 Dentistry – Handpieces and Motors
- IEC 60601-1: 2020, Consolidated Version: Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance

The results of the bench testing verify that the Star E900 Handpiece Series conform to the requirements of ISO 14457:2012 and IEC 60601-1:2020 and demonstrate substantial equivalence to the predicate devices

Biocompatibility testing was not conducted on the materials used in the Star E900 Handpiece Series. However, an assessment as conducted per the FDA guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process." The materials used in the subject device are identical to those used in the reference device, K192412, where biocompatibility testing was conducted and leveraged from.

Sterilization validation for the handpieces was performed in accordance to ANSI/AAMI ST79:2010 & A4:2013, AAMI/ANSI/ISO 14937:2009 and ANSI/AAMI ST81:2004 (R2010). Cleaning and disinfection validation was conducted per the FDA Guidance Document for "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" issued on March 17, 2015.

A risk management plan to identify any risks and the management of those risks was carried out during the design and development of the handpiece series. A risk analysis for the Star E900 Handpiece Series was conducted in accordance with ISO14971:2012. The analysis showed that the level of risk associated with the Star E900 Handpiece Series is not any greater than the level of risk associated with similar medical devices currently on the market.

IX. CONCLUSION

The Indications for Use of the Star E900 Handpiece Series is substantially equivalent to the predicate devices as are the principles of operation and design features.
The minor differences in the characteristics between the Star E900 Handpiece Series and predicate as indicated in the comparison charts do not affect the performance or Indications for Use of the proposed devices.

Based upon the comparison of technological characteristics, demonstrated through bench testing and intended use, the Star E900 Handpiece Series is substantially equivalent to the predicate devices.