January 12, 2026

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

Re: K251701
Trade/Device Name: Star E900 Electric System
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EBW
Dated: May 30, 2025
Received: June 2, 2025

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, MChE, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251701

Please provide the device trade name(s).

Star E900 Electric System

Please provide your Indications for Use below.

The Star E900 Electric System is intended for use by dental professionals in the performance of dental restoration, prophylaxis and endodontic procedures.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

I. SUBMITTER

K251701

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
May 30, 2025

II. DEVICE

Trade Name: Star E900 Electric System
Common Name: Controller, Foot, Handpiece and Cord
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I
Product Code: EBW

III. PREDICATE DEVICE

Clearance: K163402 dated August 31, 2017
Manufacturer: Nakanishi, Inc.
Trade/Device Name: NLZ Motor System
Common Name: Controller, Foot, Handpiece and Cord
Regulation Number: 21CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulation Class: Class I
Product Code: EBW

IV. REFERENCE DEVICE

Clearance: K240183
Manufacturer: DentalEZ, Inc, StarDental Division
Trade/Device Name: Star E900 Handpiece Series
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

V. DEVICE DESCRIPTION:

The Star E900 Electric System is comprised of a power supply, control unit, cable and brushless micromotor. The control unit controls the torque, speed and directional rotation of the motor. The system is programmed through the use of a color touch screen on the control unit. The motor has a rotational speed of 100-40,000 rpm's and can be operated in a clockwise or counterclockwise direction. The system also provides variable light intensity to the handpiece.

The system has two different operating modes, preparation mode for dental restorations and prophylaxis procedures and endodontic mode for endodontic procedures. Within each mode there are 10 different profile settings that can be customized by the user. Each profile can be customized for the gear ratio, speed, direction of rotation, light and for the endodontic mode, the torque can also be customized.

The motor incorporates RFID (radio frequency identification) technology**.** This passive RFID tag does not have a built-in energy source. The RFID tag allows the practitioner to track the device within the office only if the practitioner has a separate reader. The RFID reader allows the practitioner to track such things as usage and maintenance.

The control unit is programmed to detect a rise in the temperature of the handpiece, if the handpiece is equipped with a thermal sensor, in order to reduce the risk of patient injury. It will also detect if there is an overcurrent condition in the motor which could cause damage to the system.

The Star E900 Electric System is available in two different models. One model is a tabletop stand-alone unit and the other model can be integrated into a dental delivery unit.

The Star E900 Electric System uses a cellular connection to connect with the cloud. Through this connection, the system transmits data concerning the operation of the system. There is no patient information transmitted or stored on the cloud. The system cannot be operated through the cellular connection. System updates are transmitted as needed through this connection. The user has the option of accessing a web application that will allow the user to see the functions of the system.

VI. INDICATIONS FOR USE

The Star E900 Electric System is intended for use by dental professionals in the performance of dental restoration, prophylaxis and endodontic procedures.

VII. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The Star E900 Electric System, the predicate device and reference predicate have the same technological characteristics:

- Intended use
- Power source
- RFID technology
- Motor overcurrent condition sensor

The following technological differences exist between the Star E900 Electric System and the predicate devices:

- Temperature sensing software to detect the temperature of the handpiece
- Cellular connectivity for monitoring system functions and updating software.

The Star E900 Electric System 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 table summarizes the comparison between the proposed device, predicate device and the reference device.

Device	Proposed device:	Predicate:	Reference Predicate:
	Star E900 Electric System	NLZ Motor System (K163402)	Star E900 1:5 Handpiece (K240183)
Indications for Use	The Star E900 Electric System is intended for use by dental professionals in the performance of dental restoration, prophylaxis and endodontic procedures.	The NLZ Motor System is intended for use by dental professionals in the performance of dental restoration, prophylaxis and endodontic procedures	Intended to be used in general dentistry work by a trained dental professional for the removal of decayed matter, cavity and crown preparations, the removal of fillings and surface finishing of tooth and restoration surfaces.
Drive	Electronic micromotor	Electronic micromotor	Air driven
Components	Power supply, control unit, micromotor	Power supply, motor controller, electric micro motor and contra-angle handpiece	NA
Light	LED	LED	Yes – FO glass rod
Range of rotation speed	100 – 40,000 rpm	100 – 40,000 rpm	40,000 rpm max
Rotating direction	Forward and reverse	Forward and reverse	NA
Handpiece temperature sensing	Yes	Yes	Yes – for repair purposes
Motor overcurrent sensing	Yes	Yes	NA
Operating modes	Preparation mode Endodontic mode	General mode Endodontic mode – NLZ E Motor Set only	NA
Cooling air	36-43 psi	58.0 psi	36 psi
Spray water	50mL/min. @2.5 Bar (36 psi)	36 psi	29 psi
Spray air	1.5 NL/min @2.5 Bar (36 psi)	36 psi	31 psi
Sterilization	Yes – motor only	Yes	Yes

Handpiece connection	E-type (ISO 3964 – short)	E-type (ISO 3964)	NA
RFID technology	Yes	No	Yes
Cellular connectivity	Yes	No	NA

VIII. PERFORMANCE DATA

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

- ISO 14457: 2017 Dentistry – Handpieces and Motors

Electromagnetic compatibility testing in accordance with IEC 60601-1-2:2014, A1:2020 was performed. In addition, electrical safety testing in accordance with the following standards was performed.

- IEC 60601-1: 2005, Ed 3+A1; A2 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014, A1: 2020 – Medical Electrical Equipment – Part 1-2: General Requirements for basic safety and essential performance – Collateral Stand: Electromagnetic disturbances – Requirements and tests
- IEC 60601-1-6:2010, Ed. 3+A1; A2 - – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
- IEC 80601-2-60:2019 Ed. 2 – Medical Electrical Equipment – Part 2-60: Particular Requirements for the Basic Safety and Essential Performance of Dental Equipment

The results of the bench testing verify that the Star E900 Electric System conforms to the requirements of ISO 14457:2017. The results of the electromagnetic compatibility testing and electrical safety testing did not raise any concerns for the safe use of the device.

Biocompatibility testing was not conducted on the materials used in the motor of the Star E900 Electric System. However, an assessment was 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, K240183.

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 system. A risk analysis for the Star E900 Electric System was conducted in accordance with ISO14971:2012. The analysis showed that the level of risk associated with the Star E900 Electric System 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 Electric System 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 Electric System 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 Electric System is substantially equivalent to the predicate devices.