January 6, 2020

Robert Young
Senior Director of Engineering
1816 Colonial Village Lane
Lancaster, Pennsylvania 17601

Re: K192412
Trade/Device Name: SD500 Elite LubeFree High Speed Handpiece, SD500 Elite Lubricated High Speed Handpiece, SD500 Pro LubeFree High Speed Handpiece, Pro Lubricated High Speed Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EFB
Dated: October 3, 2019
Received: October 8, 2019

Dear Robert Young:

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K192412

Device Name
SD500 High Speed Handpiece Series - SD500 Elite LubeFree Handpiece, SD500 Pro LubeFree Handpiece, SD500 Elite Lubricated Handpiece, SD500 Pro Lubricated Handpiece

Indications for Use *(Describe)*
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.

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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K192412

I. SUBMITTER

DentalEZ Inc., StarDental Division
1816 Colonial Village Lane
Lancaster, PA 17601
Phone: (717) 291-1161
Contact Person:
Robert Young, Senior Director of Engineering
Kay Engle, Regulatory Affairs/QA Supervisor

September 3, 2019

II. DEVICE

Name of the Device: SD500 High Speed Handpiece Series comprised of:
SD500 Elite LubeFree High-Speed Handpiece
SD500 Pro LubeFree High-Speed Handpiece
SD500 Elite Lubricated High-Speed Handpiece
SD500 Pro Lubricated High-Speed Handpiece
Common or Usual name: High-Speed Handpiece
Classification Name: Dental Handpieces and Accessories
Regulation Number: 21 CFR 872.4200
Regulatory Class: I
Product Code: EFB

III. PREDICATE DEVICE

Primary predicate: 430 Torque High Speed Handpiece Series (K153411)
Reference device: Concentrix MX-AC High-Speed Handpiece (K173465)

IV. DEVICE DESCRIPTION:

The SD500 High-Speed Handpiece Series includes a fiber optic high speed handpiece, to be marketed as a SD500 Elite Handpiece and a non-fiber optic handpiece, to be marketed as a SD500 Pro Handpiece. Both the Elite and the Pro versions are available as lubefree or lubricated turbine handpieces. Each is a pneumatically driven handheld device with multi-port water spray that is capable of reaching rotational speeds of 367,200 – 448,800 rpms at a recommended air pressure of 38 to 43 PSI. The series delivers a range of 39 - 50 watts of power providing .28 oz.-in. of stall torque at 43 psi. The handpieces are constructed of stainless steel, including the internal air and water tubes, which provide drive air to the turbine assembly and cooling water to the work site. The handpiece also uses PEEK in its construction.

The handpieces incorporate either a lubefree ceramic bearing turbine assembly or a lubricated ceramic bearing turbine assembly. Both versions of the turbine assembly use a push button autochuck. The stainless steel and aluminum air driven turbine assembly provides rotation to the bur.

The SD500 High-Speed Handpiece Series uses a quick disconnect coupler that allows easy connection to the dental line delivery tubing. This coupler allows for easy rotation of the handpieces when attached to the tubing. These couplers include both fiber optic and non-fiber optic versions with Type 3 or 2 connections. The fiber optic version uses LED technology to deliver the light to the handpiece. All couplers are autoclavable.

The burs used with the SD500 High Speed Handpiece Series are ISO 1797-1, type 2 burs. Only burs with hardened, tempered steel shanks or carbide shanks should be used.

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. A reader will enable the practitioner to track such things as usage and maintenance.

V. INDICATIONS FOR USE

The SD500 High Speed Handpiece Series are used by trained dental professionals for a variety of procedures including but not limited to caries and amalgam removal, restorative work and crown preparations

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The SD500 High Speed Handpiece Series and the primary predicate device have the same technological characteristics:

- Intended use
- Method of operation
- Use of the same base materials for the stainless steel components
- Autoclavable

The following technological differences exist between the SD500 High Speed Handpiece Series and the predicate:

- Multi-port spray
- RFID technology

The proposed SD500 High Speed Handpiece Series and the reference device have the same technological similarities and differences as noted above for the primary predicate. In addition, the reference device incorporates a lubricated turbine assembly in the handpiece. This lubricated turbine will be incorporated into the lubricated version of the proposed handpiece.

The difference between the proposed devices and the primary predicate device is the number of water spray ports, addition of RFID technology and the addition of PEEK (Polyether Ether Ketone) to the base materials. These differences do not affect the performance or safety of the device.

The following table summarizes the comparison of the proposed SD500 High Speed Handpiece Series to the primary predicate device and the reference device for indications for use and technological characteristics.

Device	Proposed device: SD500 High Speed Handpiece Series	Primary Predicate: 430 Torque High Speed Handpiece Series comprised of: 430 SWL Torque High Speed Handpiece and 430 SW Torque High Speed Handpiece (K153411)	Reference Device: Concentrix MX-AC High Speed Handpiece (K173465)
Indications for Use	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	The 430 Torque High-Speed Handpiece Series are used by trained dental professionals for a variety of procedures including but not limited to caries and amalgam removal, restorative work and crown preparations	The Concentrix MX-AC High-Speed Handpiece 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.
Product Code	EFB	EFB	EFB
Operational Mode	Air driven	Air driven	Air Driven
Type of chuck	Autochuck	Autochuck	Autochuck
Operating Pressure	38-43 PSI	38-43 PSI	32 PSI
Coupling Type	ISO 9168,Type 3,Type 2	ISO 9168, Type 3	ISO 9168, Type 1
Bur Dimension	ISO 1797-1, Type 2	ISO 1797-1, Type 2	ISO 1797-1, Type 2
Material composition	Stainless steel PEEK (Polyether Either Ketone)	Stainless steel	Stainless steel
Components	High speed pneumatic driven handpiece with option of lube-free or lubricated ceramic bearings autochuck turbine assembly Pushbutton end cap Swivel coupling RFID tag	High speed pneumatic driven handpiece. Lubricated ceramic bearings Autochuck turbine assembly Pushbutton end cap Swivel coupling	High speed pneumatic driven handpiece Lubricated steel bearing autochuck turbine assembly. Pushbutton end cap Swivel coupling
Biocompatibility	Stainless steel PEEK Ceramic bearings	Stainless steel Ceramic bearings	Stainless steel Steel bearings
Sterilization	Sterilization validation in accordance with ANSI/AAMI ST79:2010 & A4:2013, AAMI/ANSI/ISO 14937:2009 & ANSI/AAMI ST81:2004 (R2010)	Sterilization validation in accordance with ANSI/AAMI ST79:2010 & A4:2013, AAMI/ANSI/ISO 14937:2009 and NSI/AAMI ST81:2004 (R2010)	Sterilization validation in accordance with ANSI/AAMI ST79:2010 & A4:2013, AAMI/ANSI/ISO 14937:2009 and NSI/AAMI ST81:2004 (R2010)

Device	Proposed device: SD500 High Speed Handpiece Series	Primary Predicate: 430 Torque High Speed Handpiece Series comprised of: 430 SWL Torque High Speed Handpiece and 430 SW Torque High Speed Handpiece (K153411)	Reference Device: Concentrix MX-AC High Speed Handpiece (K173465)
Performance	Capable of reaching rotational speed of 367,200 to 448,800 at a recommended air pressure of 38 - 43 PSI; delivers a range of 39 - 50 watts of power providing .28 oz.-in. of stall torque. Performance testing in compliance with ISO 14457:2012 – Dentistry – Handpieces and Motors	Capable of reaching rotational speeds of 360,000 to 450,000 rpms at a recommended air pressure of 38-43 PSI; delivers on average 20 watts of power providing .269 oz.-in. of stall torque. Performance testing in compliance with ISO 14457: 2012 Dentistry – Handpieces and Motors	Variable 302,000 rpm +/- 10% Performance testing in compliance with ISO 14457:2012 Dentistry – Handpieces and Motors
Risk analysis	ISO14971:2012 Medical devices – Application of risk management to medical devices	ISO14971:2012 Medical devices – Application of risk management to medical devices	ISO14971:2012 Medical devices – Application of risk management to medical devices

VII. PERFORMANCE DATA

The following tests were conducted to evaluate the functional performance and safety of the SD500 High Speed Handpiece Series:

- ISO 14457: 2017 Dentistry – Handpieces and Motors
- IEC 60601-1:2005 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance

The test results confirm that the SD500 High Speed Handpiece Series conform to the requirements of ISO 14457:2012 and IEC 60601-1:2005 and are substantially equivalent for use as high speed handpieces.

Biocompatibility testing was not conducted on the materials used in the SD500 High Speed Handpiece Series. The materials used in these handpieces are widely known and used within the dental and medical device industry.

Sterilization validation for the handpieces which incorporate the turbine assemblies 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 analysis for the SD500 High Speed Handpiece was developed using ISO14971:2012.

VIII. CONCLUSION

Based upon the comparison of technological characteristics, demonstrated through bench testing and intended use, the SD500 High Speed Handpiece Series is as safe and effective as the predicate devices.