



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 4, 2016

Dentalez, Inc.
Mr. Dan Laskowitz
Engineering/Quality Manager
1816 Colonial Village Lane
Lancaster, Pennsylvania 17601

Re: K153411

Trade/Device Name: 430 Torque High-speed Handpiece Series
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I
Product Code: EFB
Dated: March 7, 2016
Received: March 8, 2016

Dear Mr. Lashkowitz:

This letter corrects our substantially equivalent letter of April 8, 2016.

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 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Susan Runna DDS, MA". The signature is written in a cursive style. A faint, large "FDA" watermark is visible in the background behind the signature.

Erin I. Keith, M.S.

Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153411

Device Name

430 Torque High Speed Handpiece Series - 430 SWL Torque High Speed Handpiece, 430 SW Torque High Speed Handpiece

Indications for Use (Describe)

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 preparation.

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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DentalEZ, Inc. StarDental Division 510(k) Premarket Notification 430 Torque High-Speed Handpiece Series	510(k) Summary
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I. SUBMITTER

DentalEZ Inc., StarDental Division
1816 Colonial Village Lane
Lancaster, PA 17601
Phone: (717) 291-1161
Fax: (717) 391-2757
Contact Person:
Dan Laskowitz, Engineering/Quality Manager
Kay Engle, Regulatory Affairs Supervisor/QA
Date prepared: March 7, 2016

II. DEVICE

Name of Device: 430 Torque High Speed Handpiece Series comprised of:
430 SWL Torque High Speed Handpiece
430 SW Torque High Speed Handpiece
Common or Usual Name: High Speed Handpiece
Classification Name: Handpiece, Air-powered, Dental (21 C.F.R. § 872.4200)
Regulatory Class: I
Product Code: EFB

III. PREDICATE DEVICE:

Primary predicate: 430 SW Non-Fiber Optic Handpiece (K902402)
Reference predicate: 430 Series High Speed Handpiece (K982593 and K960719)

IV. DEVICE DESCRIPTION:

The 430 Torque High-Speed Handpiece Series consists of a fiber optic high speed handpiece, marketed as a SWL and a non-fiber optic handpiece, marketed as a SW handpiece. Each is a pneumatically driven hand-held device that is capable of reaching rotational speeds of 350,000 to 450,000 rpms at a recommended air pressure of 38-43 PSI. The series delivers on average up to 20 watts of power providing .269 oz.-in. of stall torque.

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 stainless steel and aluminum air driven turbine assembly provides spin to the bur, and incorporates lubefree ceramic bearings (K905155) and a push button autochuck. The rotor is larger than the rotor of the predicate, yielding a higher cutting torque.

The fiber optics in the SWL version of the handpiece are lead-free, multi-core glass rod that transmit light from the fiber optic swivel coupler to the oral cavity.

The 430 Torque High-Speed handpiece Series can be assembled to quick disconnect couplers that are ISO Type 3 and ISO Type 2 connections, available as fiber optic or non-fiber optic versions, using a halogen bulb or LED technology. All couplers are autoclavable with the exception of the LED coupler that incorporates the electronics internally.

The following describes the improvements that have been made to the 430 Series High-Speed Handpiece and 430 SW Non-Fiber Optic Handpieces since the last 510(k) clearances, which have also been incorporated into the 430 Torque High-Speed Handpiece Series:

1. The fiber-optics used in the SWL version of the handpieces changed from bundled fiber optics to twin-fused solid rod fiber optics.
2. The finish of the outer housings on the handpieces has been modified to have a dull appearance (satin) through a process called bead blasting. This is an aesthetic change only and does not affect the performance of the handpiece. The finish of the outer housing on the handpieces continues to be available in the glossy finish as cleared on the predicate devices.

V. INDICATIONS FOR USE:

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The 430 Torque High-Speed Handpieces and the primary predicate device are both air-driven handpieces used to perform a variety of dental procedures. The proposed devices and the primary predicate device have the same technological characteristics:

- Single water spray without cooling air
- Push button autochuck turbine assembly
- Bur extraction force
- Use of the same materials
- No lubrication required
- Autoclavable
- Connect to coupler – allow for ease of rotation on tubing

The following technological differences exist between the 430 Torque High-Speed Handpiece and the primary predicate:

- Free run speed (handpiece speed in RPM with no load applied)
- Power
- Stall torque

The proposed 430 SWL Torque High-Speed Handpiece and the reference predicate device have the same technological similarities and differences as noted above for the primary predicate. In addition, the reference predicate incorporates fiber optics for illumination of the work area. The fiber optics used in the reference predicate device are incorporated in the proposed 430 SWL Torque High-Speed Handpiece.

The following table summarizes the comparison of the 430 Torque High-Speed Handpieces Series to the primary predicate device and reference predicate for indications for use and technological characteristics.

Device	Submission device K153411 430 Torque High Speed Handpiece Series	Primary predicate K902402 SW Non-Fiber Optic Handpiece	Reference predicates K982593 and K960719 430 Series High Speed Handpiece
Indications for Use	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.	High-speed dental handpieces used by trained dental professionals for drilling in the oral cavity for procedures including but not limited to caries removal, restorative work and crown preparations.	High-speed dental handpieces used intraorally by trained dental professionals for drilling and preparation of dental caries for restoration such as fillings.
Material composition	Stainless steel, aluminum; optional bead blasted outer surface	Stainless steel, aluminum	Stainless steel, aluminum
Components	High speed pneumatic driven handpiece with option of twin fused solid rod fiber optic with ceramic lube free bearings	High speed pneumatic driven handpiece with ceramic bearings	High speed pneumatic driven handpiece with ceramic bearings with option of bundled fiber optics; autochuck and lube free bearings
Biocompatibility	Identical material composition and manufacturing process to the predicates	The design incorporates either 400 series stainless steel or 300 series stainless steel for device construction. These materials are known for their corrosion resistance and are biocompatible with tissue encountered during use.	The design incorporates either 400 series stainless steel or 300 series stainless steel for device construction. These materials are known for their corrosion resistance and are biocompatible with tissue encountered during use. These materials are identical to the predicate 430 series high speed

			handpiece currently manufactured by Star Dental.
Sterilization	Sterilization validation in accordance with ANSI/AAMI ST79:2010 & A4:2013, AAMI/ANSI/ISO 14937:2009 and ANSI/AAMI ST81:2004 (R2010)	Sterilization validation report references AAMI TIR No. 12-1994	Sterilization validation carried out in accordance with the FDA June 1996 guidance document to dental handpiece manufacturers.
Performance	Capable of reaching rotational speeds of 350,000 to 450,000 rpms at a recommended air pressure of 38-43 PSI; delivers on average up to 20 watts of power providing .269 oz.-in. of stall torque. Performance testing in compliance with ISO 14457:2012 Dentistry – Handpieces and motors	Capable of reaching rotational speeds of 430,000 rpms at a recommended air pressure of 30 PSI; delivers on average 14 watts of power providing .181 oz.-in. of stall torque. Performance testing in compliance with ISO 7785-1 Dental Handpieces – Part 1: High-speed air turbine handpieces	Capable of reaching rotational speeds of 430,000 rpms at a recommended air pressure of 34 PSI; delivers on average 14 watts of power providing .181 oz.-in. of stall torque. Performance testing in compliance with ISO 7785-1 Dental Handpieces – Part 1: High-speed air turbine handpieces
Risk analysis	ISO14971:2012 Medical devices – Application of risk management to medical devices	Risk analysis at time of submission unknown. Current risk analysis per ISO14971:2012 – Application of risk management to medical devices.	Risk analysis at time of submission unknown. Current risk analysis per ISO14971:2012 – Application of risk management to medical devices.

VII. PERFORMANCE DATA

Performance testing was completed in accordance with ISO 14457:2012 Dentistry – Handpieces and motors.

Sterilization validation for the sterilization of the handpieces was performed in accordance to ANSI/AAMI ST79:2010 & A4:2013, AAMI/ANSI/ISO 14937:2009 and ANSI/AAMI ST81:2004 (R2010).

A risk analysis for the 430 Torque High-Speed Handpiece Series was developed using ISO14971:2012.

VIII. CONCLUSION

Based upon the comparison of technological characteristics, demonstrated through bench testing and intended use, the 430 Torque High-Speed Handpiece Series is substantially equivalent to the predicate devices.