DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 19, 2017

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

Re: K162397
Trade/Device Name: Titan 3 Low Speed Angle Attachments
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EGS
Dated: December 5, 2016
Received: December 22, 2016

Dear Dan Laskowitz:

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. 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" (21 CFR 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K162397

Device Name
Titan 3 Low Speed Angle Attachments

Indications for Use *(Describe)*
Titan 3 Low Speed Angle Attachments are used intraorally by trained dental professionals for drilling and preparation of dental cavities for restoration, such as fillings, as well as disking, cavity and crown preps, polishing, post and pin drilling and pin setting.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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I. SUBMITTER

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Contact Person:
Dan Laskowitz, Engineering/Quality Manager
Kay Engle, Regulatory Affairs/QA Supervisor

August 4, 2016

II. DEVICE

Name of the Device: Titan 3 Low Speed Angle Attachments

Common or Usual Name: Angle Attachments for Low-Speed Handpiece
Classification Name: Dental Handpiece and Accessories (21 C.F.R. § 872.4200, Product code EGS)
Regulatory Class: I
Product Code: EGS

III. PREDICATE DEVICE

Titan 3 LubeFree Motor Attachments (K983574)

IV. DEVICE DESCRIPTION:

The proposed angles are attached to a pneumatically driven low speed motor via the use of either a motor-to-angle adaptor (K960260) or 16:1 contra angle (pre-amendment). Air supplied to the motor (K960260) drives a gearing system through the adaptor or contra angle to the angle attachment. A torque multiplier can be used between the motor and motor-to-angle adaptor or contra angle to reduce the rpms from the motor while increasing the torque. A dental bur is inserted into the angle to perform the procedure.

There are four different angle styles that will marketed under the names Titan 3 LubeFree Angles, Titan 3 Lubricated Angles, and Five Star Prophy Angles with some variations within each style. The main differences between the styles of the proposed angles are in the mechanical chucking mechanism of the angle and prophy, the composition of the outside plating of the angle attachment and the lubrication that may be needed to maintain the attachment.

The angles are constructed of brass, which is chrome plated The internal drive gears are constructed of stainless steel.
The lubricated angles, consisting of a ball bearing manual latch angle, ball bearing auto latch angle, ball bearing auto chuck friction grip angle and a Prophy angle require daily lubrication using the recommended lubricant, Dentalube II, which is manufactured by StarDental (K070869).
The lubefree angles, consisting of a ball bearing manual latch angle, ball bearing auto latch angle, ball bearing auto chuck friction grip angle and a Prophy angle, are lubricated during the assembly process and require no further lubrication by the user.
All proposed angles are autoclavable.

V. INDICATIONS FOR USE

Titan 3 Low Speed Angle Attachments are used intraorally by trained dental professionals for drilling and preparation of dental cavities for restoration, such as fillings, as well as disking, cavity and crown preps, polishing, post and pin drilling and pin setting.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The Angle Attachments for Low-Speed Handpieces and the predicate devices are both attached to an air-driven low speed motor assembly. The proposed devices and the predicate devices have the same technological characteristics:

- Method of operation
- Use of the same base materials
- Lubrication requirements
- Style of angles
- Autoclavable

The difference between the proposed devices and the predicate devices are

- OEM manufacturer

The following table summarizes the comparison of the Angle Attachments for Low-Speed Handpieces to the predicate devices for indications for use and technological characteristics.

Device	Submission device Titan 3 Low Speed Angle Attachments	Predicate device K983574 StarDental Titan 3 LubeFree Motor Attachments
Indications for Use	Used intraorally by trained dental professionals for drilling and preparation of dental cavities for restoration, such as fillings, disking, cavity and crown preps, polishing, post and pin drilling and pin setting.	Used intraorally by trained dental professionals for drilling and preparation of dental cavities for restoration, such as fillings. Furthermore, the intended use extends to disking, cavity and crown preps, polishing, post and pin drilling and pin setting.
Material composition	Brass	Brass
Components	Manual latch angle Autolatch angle Autochuck angle Prophy angle	Manual latch angle Autolatch angle Autochuck angle Prophy angle
Biocompatibility	Identical material composition as the predicate	The design incorporates chrome plated brass for device construction. The drive shaft utilizes 300 series stainless steel. These materials are known for their corrosion resistance and are biocompatible with tissue encountered during use.
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
Performance	Variable up to 20,000 rpm	Variable up to 20,000 rpm
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.

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 Angle Attachments for Low-Speed Handpieces was developed using ISO14971:2012.

VIII. CONCLUSION

Based upon the comparison of technological characteristics, demonstrated through bench testing and intended use, the Titan 3 Low Speed Angle Attachments are substantially equivalent to the predicate devices.