November 7, 2022

Lares Research
Bruce Holderbein
Director of Engineering and Regulatory Affairs
295 Lockheed Ave
Chico, California 95973

Re: K220874
Trade/Device Name: Smooth Drive contra angle and straight handpieces
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EGS
Dated: October 3, 2022
Received: October 11, 2022

Dear Bruce Holderbein:

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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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Respiratory, ENT and Dental Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220874

Device Name
Smoothdrive 1:5 contra angle handpiece

Indications for Use *(Describe)*
Products intended for professional use
only. Used in general dentistry for restoration procedures.

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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Section 5 - 510(k) Summary

K220874

Submitter **807.92(a)(1)**

Lares Research
295 Lockheed Ave
Chico, Ca 95973

Contact person: Bruce Holderbein
Telephone: 530-345-1767 extension 2862
Date prepared: September 23, 2022

Device Name **807.92(a)(2)**

Trade Names: Smoothdrive 1:5 contra angle handpiece

Common Name: Contra Angle Handpiece
Classification Name: Handpiece, Contra-Angle Attachment, Dental
Regulation Number: 21 CFR 872.4200
Classification Code: EGS

Predicate Devices **807.92(a)(3)**

Predicate Device (primary): Bien Air Dental - CA Classic 1:5 L K983183
Predicate Device (secondary, for biocompatibility material comparison): KaVo 25 LPA 1:5 contra angle K073478

Device Description **807.92(a)(4)**

The Lares Research Smoothdrive 1:5 contra angle is a high-speed dental handpiece which is driven by an electrical motor. The device is designed to be connected to ISO 3964 compatible electric motors operating between 0 and 40,000 rpm. The device has a 1:5 speed increasing transmission (identified by the industry standard red ring) which translates to a working end speed of 0 to 200,000 rpm. The device has a push button chucking system is designed to allow convenient bur changing for ISO 1797 type 3 burs.
Bien Air Dental offers their Classic line of electric motor driven handpieces with the same intended use and substantially equivalent device design with model designations of CA 1:5 L contra angle handpieces.

Indications for Use **807.92(a)(5)**

Section 5 - 510(k) Summary

Lares Research Smoothdrive 1:5 contra angle handpiece is intended for professional use only. The device is used in general dentistry for restoration procedures.

Device Technological Characteristics **807.92(a)(6)**

Summary Table of Technological Characteristics

Product	Lares Research Smoothdrive 1:5 contra angle	Bien Air Dental Classic CA 1:5 L	KaVo 25 LPA 1:5 contra angle
Motor connection	ISO 3964 type 3	ISO 3964 type 3	ISO 3964 type 3
Transmission	1:5 speed increasing	1:5 speed increasing	1:5 speed increasing
Chucking system	Push button ISO 1797 type 3 compatible	Push button ISO 1797 type 3 compatible	Push button ISO 1797 type 3 compatible
Motor speed	0-40k rpm	0-40k rpm	0-40k rpm
Bur rotating speed	0-200k rpm	0-200k rpm	0-200k rpm
Fiber optic	Yes	Yes	Yes
Autoclavable	Yes	Yes	Yes

Nonclinical Tests Discussion **807.92(b)(1)**

Nonclinical tests included:

Performance tests were conducted in-house at Lares Research with production samples of the Smoothdrive 1:5 contra angle. The contra angle motor connection, speed, sound, temperature and chucking mechanism were all evaluated during validation testing. Validation testing concluded the device meets all of the applicable consensus standards.

Clinical Test Discussion **807.92(b)(2)**

No clinical field trials have been conducted with the Lares Research Smoothdrive 1:5 contra angle handpiece.

Conclusion **807.92(b)(3)**

Information in this submission provides data confirming the Lares Research Smoothdrive 1:5 contra angle handpiece is substantially equivalent to the predicate Bien Air Classic 1:5 L handpiece when used as intended. Both devices are equally safe and effective when used as intended for general dentistry restorative

procedures when coupled to a 0 – 40k rpm ISO 3964 type 3 compatible electric dental motor.