December 15, 2022

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

Re: K220873
Trade/Device Name: Perceptive electric dental motor and control unit
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit And Accessories
Regulatory Class: Class I, reserved
Product Code: EIA
Dated: November 16, 2022
Received: November 17, 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
OHT1: Office of Ophthalmic, Anesthesia,
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220873

Device Name
Perceptive electric dental motor and control unit

Indications for Use *(Describe)*
This device is intended for use in general dentistry and restorative dentistry by dentists and dental professionals in a dental office.

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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Section 5 – 510k Summary – Perceptive electric dental motor and control

K220873

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: March 21, 2022

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

Trade Names: Perceptive electric dental motor and console
Common Name: Dental motor and control
Classification Name: Operative dental unit
Regulation Number: 21 CFR 872.6640
Classification Code: EIA

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

Predicate Device (primary): Bien Air Dental – Optima MCX, K042759

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

The Lares Research Perceptive electrical motor and control is an air-to-electric dental unit for use in dental restoration and prophylaxis procedures. The unit includes a power supply, control unit, user display tablet, hose and a brushless motor. The control unit is programmable to adjust motor speed, motor direction, and light intensity. The inputs to the control unit are supplied by an electronic tablet which is connected to the unit via a USB cable. The electronic tablet Perceptive application accepts both finger touch and a limited set of voice commands. The motor speed can also be controlled via the pneumatic footswitch connected to the control unit. The unit is designed to control the motor to drive ISO 3964 compatible contra angle and straight dental handpieces at an output speed of 1,000 to 40,000 rpm.

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

Lares Research Perceptive electric motor and control unit and Bien Air Dental Optima MCX predicate device are intended for professional use for general dentistry for and dental restoration procedures. The user motor controls for

restorative dental procedures for the Perceptive and the predicate device are equivalent when industry standard 1:5 or 1:1 contra angle or straight handpieces are used. Both devices are safe and effective when used in general dentistry and dental restoration procedures.

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

The Lares Research Perceptive electric motor and control unit and the predicate device include a power supply, control unit, hose, motor. The Perceptive unit also has an electronic tablet user interface taking the place of the manual control knob and switch used on the predicate device.

Power supply

Both units use a universal input voltage medical grade power supply to isolate the mains voltage from the user and patient and provide 32 VDC to the console.

Console and user interface

Both units have user controls to set the motor speed via the console. The Bien Air Dental unit has manual controls on the console, and the Perceptive unit uses a USB port to provide a graphical user interface (finger touch) to control the motor speed, direction and light. The Lares Research Perceptive software application also accepts a limited number of user voice commands (via the connected tablet) to set motor speed and direction, and motor light on or off. The voice control for the Perceptive unit is an identical set of commands designed to set the motor speed and direction and turn the light on or off. The Lares Research Perceptive and the Bien Air Dental Optima MCX units are designed for the user's foot-operated rheostat to control the motor start and stop commands. Both consoles connect to an ISO 9168 compatible dental tubing to supply cooling air, spray air and water to a contra angle or straight handpiece attachment.

Motor

The Lares Research Perceptive electric motor and control unit and the predicate device include a small, brushless motor with permanent magnets which operates from 1,000 to 40,000 rpm and is removable from the control cable and can be safely sterilized between patients. The motors for both units have an ISO 3964 E-type connection which accepts dental handpieces with the same standard design. The Lares Research Perceptive unit includes a safety program feature which senses motor current to operationally, visually and audibly warn the operator of potential attachment failure.

Section 5 – 510k Summary – Perceptive electric dental motor and control

Summary Table of Technological Characteristics

Product	Lares Research Perceptive	Bien Air Dental Optima MCX
Power supply		
Input voltage	100-240 VAC 50 - 60 Hz	100-240 VAC 47 - 63 Hz
Output power (watts)	130	160
Control unit		
Dental unit input	ISO 9168 type 2 input	ISO 9168 type 2 input
Power input	32 VDC	32 VDC
User interface	Electronic tablet	Manual control knob and switch
Device control	Motor speed, motor direction and light	Motor speed and motor direction
Motor drive safety control	Motor drive current limit – motor drive current is reduced with visual and audible user alerts	The motor control card stops the motor if the motor is locked for more than 2 seconds or becomes hot.
System error notifications	User display errors for motor connection fault and motor drive fault	Motor stops or doesn't start
Motor		
Construction	Brushless type, 3 phase motor, synchronous with permanent magnets	brushless type with permanent magnets
Motor light (LED)	Variable from 10 - 28 kLux	Yes
Sterilizable	Yes	Yes
Lubrication	Maintenance free	Maintenance free
Warranty	2 years	3 years

Nonclinical Tests Discussion 807.92(b)(1)

Nonclinical tests included:

Performance tests were conducted in-house usability testing at Lares Research using prototype Preceptive electric dental control units. The motor speed, direction and light output were evaluated for finger-touch and voice command operation during validation testing. The Lares Research Preceptive unit maintained control of the motor speed, direction and light output.

Clinical Test Discussion 807.92(b)(2)

No clinical field trials have been conducted with the Lares Research Perceptive electric dental motor and control unit.

Conclusion 807.92(b)(3)

Information included in this submission provides data confirming the Lares Research Perceptive dental motor and control unit is substantially equivalent to

Section 5 – 510k Summary – Perceptive electric dental motor and control

the predicate Optima MCX motor and control unit. Both devices have the same basic system motor speed and direction controls and the same intended use. The Lares Research Perceptive unit also allows the user to control the light output and has an electronic tablet to provide improved feedback for device settings and status and allow a limited set of voice commands. Both units are equally safe and effective when used as intended for general dentistry and dental restorative procedures when coupled with contra angle or straight 1:5 speed increasing or 1:1 direct drive ISO 3964 type 3 connection handpieces.