DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Ortek Therapeutics, Inc.
% Allison Komiyama
Principal Consultant
AcKnowledge Regulatory Strategies
2834 Hawthorn St.
San Diego, California 92104

September 11, 2017

Re: K170822
Trade/Device Name: Electronic Caries Detector
Regulation Number: 21 CFR 872.1745
Regulation Name: Caries Detection Device
Regulatory Class: Class II
Product Code: NBL, LFC
Dated: August 10, 2017
Received: August 11, 2017

Dear Dr. Allison Komiyama:

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 (DICE) 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 (DICE) 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,

Mary S. Runner -S

for
Lori Wiggins
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)*
K170822

Device Name
Electronic Caries Detector

Indications for Use *(Describe)*
The Electronic Caries Detector is for use by dental professionals as an aid in the diagnosis and monitoring of dental caries.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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510(k) Summary
K170822

DATE PREPARED
September 5, 2017

MANUFACTURER AND 510(k) OWNER
Ortek Therapeutics, Inc.
4 Expressway Plaza, Roslyn Heights, NY 11577, USA
Telephone: +1 (516) 484-4500
Email: mgoldberg.ortek@gmail.com
Official Contact: Mitch Goldberg, President

REPRESENTATIVE/CONSULTANT
Allison C. Komiyama, Ph.D., R.A.C.
AcKnowledge Regulatory Strategies
Telephone: +1 (619) 208-7888
Email: akomiyama@acknowledge-rs.com

TRADE/PROPRIETARY NAME OF SUBJECT DEVICE
Electronic Caries Detector

COMMON NAME
Laser Fluorescence Caries Detection Device

DEVICE CLASSIFICATION
Laser fluorescence caries detection device

PRODUCT CODE
NBL, LFC

REGULATION NUMBER
21 CFR 872.1745

PREMARKET REVIEW
ODE/DAGRID/DEDB
Dental Panel

INDICATIONS FOR USE
The Electronic Caries Detector is for use by dental professionals as an aid in the diagnosis and monitoring of dental caries.

510(k) Summary

DEVICE DESCRIPTION

The ECD is a portable instrument that provides an electrical current source, a meter with a digital read-out between 00 and 100, and indicator and reference electrodes to aid in the detection and monitoring of non-cavitated and cavitated caries lesions in teeth.

The ECD indicator electrode is comprised of a replaceable, single-use, stainless steel probe tip. This component is sized and dimensionally configured to achieve close contact with the tooth being examined. The tip ensures electrical contact with dentinal fluid at sites that are not readily accessible or evaluated using traditional means. The ECD indicator electrode is paired with a reference electrode to complete the necessary electrical circuit. The reference electrode is a stainless steel lip hook that rests on the patient's lower lip.

The device is powered by a 9 volt alkaline battery, regulated down to 5 volts. The unit has a 2 ½ digit LCD display, two timer circuits, and a beeper. The first timing circuit is triggered upon circuit completion. The beeper sounds for 3 seconds, the probe is then removed, and the second timer holds the display for 5 seconds. Then the display returns to zero, ready for the next measurement.

PREDICATE DEVICE IDENTIFICATION

The Electronic Caries Detector is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K090598	CarieScan Pro – Cariescan LLC	✓
K982105	Oral Potential Meter – Pertec of Wisconsin, Inc.	

SUMMARY OF NON-CLINICAL AND CLINICAL TESTING

No FDA performance standards have been established for Electronic Caries Detector. The following tests were performed to demonstrate substantial equivalence, based on current industry standards:

- Biocompatibility (per ISO 10993)
- In vitro performance testing on extracted teeth
- In vivo performance testing on teeth before and after extraction

The results of these tests indicate that the Electronic Caries Detector is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES

Ortek believes that the Electronic Caries Detector is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has similar design, technological characteristics, and uses similar or identical materials as the devices cleared in K090598 and K982105. The subject device has identical indications for use as the device cleared in K090598 and identical intended use as the devices

cleared in K090598 and K982105. The ECD uses electrical conductance similar to the device cleared in K982105. The power source of the subject device differs compared to both predicates, however, it uses a lower voltage battery (9V) than the primary predicate (110V). Performance testing of the subject device is similar to the performance of the primary predicate, however, the ECD used a comparison to biopsy whereas the primary predicate compared to visual-tactile scores of the evaluated teeth. Ortek believes that biopsy is considered the current gold standard and the performance scores are more significant compared to visual-tactile readings.

CONCLUSION

The Electronic Caries Detector is considered substantially equivalent to the predicate devices based on the testing performed, the identical indications for use, and similar technological characteristics. Based on the testing performed, including biocompatibility, performance and clinical testing, it can be concluded that the subject device does not raise new issues of safety or efficacy compared to the predicate devices.

Substantial Equivalence Summary	***Subject Device***	***Primary Predicate***	***Reference Predicate***
	Ortek Therapeutics, Inc. Electronic Caries Device K170822	CarieScan Ltd CarieScan PRO K090598	Pertec of Wisconsin, Inc. Oral Potential Meter (OPM) K982105
Indications for Use	The Electronic Caries Detector is for use by dental professionals as an aid in the diagnosis and monitoring of dental caries.	For use by dental professionals as an aid in the diagnosis and monitoring of dental caries.	The Oral Potential Meter aids the dental professional in detecting potential caries. Measurements above 10 millivolts, 1 microamp and 0.01 microwatts x seconds indicates a need for the dental professional to look at potentially carious leasions by also using other means, such as direct exploration, radiographs, etc. The OPM aids in determining potentially active caries and can not detect mineralized caries that have no potenial energy. Remineralized teeth are no longer considered carious. The OPM is a device that measures and displays voltage and conducts through caries related to metallic restorations in the oral cavity. The dentist may be able to, on visual exam, detect caries at the margins or with x-ray under a restoration with these readings. It also provides a power measurement (energy or joules) integrated over a measured period of time and displays it. The meter has two probes that are used to make the measurements. One is a reference probe, Red, with push-button switch to turn on the meter and initiate the measurements. The other is used as the primary input, Black to the meter's electronics
Device Info			
ProCodes / Reg #	NBL / 21 CFR 872.1745	NBL / 21 CFR 872.1745	LFC / 21 CFR 872.1740
Class	II	II	II
Intended use	Aid in caries detection	Aid in caries detection	Aid in caries detection
Where used	Dental office	Dental office	Dental office
Energy used and/or delivered	Electrical conductance	Electrical impedance	Electrical conductance
Technological Characteristics			
Power source	9 V, alkaline battery	110 V, Lithium polymer rechargeable battery	Alternating current (AC)
Measurement method	Measurement of conductance	Comparison of impedance at multiple frequencies	Measurement of conductance, voltage, and time
Performance	When compared to biopsy: 92% sensitivity 100% specificity	When compared to visual-tactile: 92.5% sensitivity 92.5% specificity	Unknown
Maximum applied current	< 10 µA	< 10 µA	10 µA
Indicator electrode	Probe tip (stainless steel)	Probe tip sensor	Probe tip (stainless steel)
Provided sterile?	No	Yes	No
Sterilization method	Steam	Steam	Steam
Single use?	Yes	Yes	No
Reference electrode	Stainless steel lip hook (reusable)	Stainless steel lip hook (reusable)	Stainless steel
Test range	0-100	0-100	Unknown