September 1, 2023

Perimetrics, Inc.
℅ Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K232657
Trade/Device Name: InnerView LC
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories
Regulatory Class: Class I, reserved
Product Code: EKX
Dated: August 28, 2023
Received: August 31, 2023

Dear Dave Yungvirt:

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
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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)*
K232657

Device Name
InnerView LC

Indications for Use *(Describe)*
The InnerView LC is intended to precisely measure the damping characteristic of the periodontium and its associated fixed structures (teeth and/or implants). It can provide data to quantify tooth and/or dental implant mobility.

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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510(k) Summary

I. SUBMITTER

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Contact Person: Alicia Mszyca
Tel. 714-325-9887

Date Prepared: June 30, 2023
Date Updated: August 14, 2023

II. DEVICE

Trade Name:	InnerView LC
Common Name:	Dental Handpiece
Classification Name:	Handpiece, Direct Drive, AC-Powered (21 CFR 872.4200)
Device Class:	I
Product Code:	EKX

III. PREDICATE DEVICE

Primary Predicate Device:	Perimetrics Inc., Periometer, K072213
Reference Device:	Osstell AB, Osstell Beacon K181888

IV. DEVICE DESCRIPTION

The InnerView LC is an electromagnetically driven percussion system used to collect the percussion data of teeth and/or implants by the dental professional. The system is indicated to precisely measure the damping characteristics of the periodontium and its associated fixed structures (teeth and/or implants). It can provide data to quantify tooth and/or dental implant mobility.

The InnerView LC consists of a wireless hand-held handpiece, base station, disposable film tip, and software. A USB cable provides a connection from the base station to a PC.

The device utilizes non-invasive quantitative percussion diagnostics (QPD), a mechanics-based methodology that tests the damping capability, and consequently mobility of teeth and dental implants by lightly percussing their buccal surface. The percussion data generated by the handpiece is wirelessly transferred to the base station and forwarded to the PC via the USB connection. In addition, the base station acts as a handpiece battery charger when the handpiece is docked. The device requires a fresh single use disposable film tip to be attached to the handpiece prior to each new procedure.

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V. INDICATIONS FOR USE

The InnerView LC is intended to precisely measure the damping characteristics of the periodontium and its associated fixed structures (teeth and/or implants). It can provide data to quantify tooth and/or dental implant mobility.

The indication for use statement for the InnerView LC is identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The InnerView LC functions in a manner similar to and is intended for the same use as the Periometer, an electromagnetically driven percussion system used to precisely measure damping characteristics of the periodontium and its associated fixed structures (teeth and/or implants). It can provide data to quantify tooth and/or dental implant mobility.
The handpieces have the same mechanism of action, light percussion on the buccal side of the tooth/implant, same data acquisition through the piezo sensor which detects the amount of force absorbed by tooth/implant from the percussion probe, same user interface and output of results (energy return graph and loss coefficient), percussion /tapping mechanism material, maximum contact/tapping forces and the way data is transferred to the PC from the base station through USB connection.

Technological differences between the InnerView LC and the predicate device include:

- The InnerView LC is used with single use disposable film tips to minimize cross-contamination potential. In addition, each tip is equipped with a security chip which communicates with the handpiece to register only one tip for a single patient procedure.
- Not possible to sterilize. Instead, the device must be cleaned and disinfected between patients, and used with a transparent, commercially available barrier sleeve, as indicated in the User Manual.
- Handpiece is battery driven and wirelessly connects with the base station and transfers the percussion data. The handpiece charges when docked and cannot be used while charging.
- The device uses a cloud platform for storing generated percussion data for each patient and calculating the loss coefficient.
- The InnerView LC is factory calibrated for ease of use.

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Table 1: Device Comparison Table

Characteristics	Subject device	Predicate device	Reference device	Comparison subject vs predicate
	InnerView LC (subject device)	**Periometer K072213**	**Osstell Beacon K181888**	
Product code	EKX	EKX	EKX	Same
Intended use	InnerView LC is used to collect the tooth/implant percussion data by the dental professional.	Periometer Instrument is used to collect the tooth/implant percussion data by the dental professional.	Dental implant stability analyzer	Same
Indications for Use	InnerView LC precisely measures the damping characteristics of the periodontium and its associated fixed structures (teeth and/or implants). It can provide data to quantify tooth and/or dental implant mobility.	Periometer is a unit that precisely measures the damping characteristics of the periodontium and its associated fixed structures (teeth and/or implants). It can provide data to quantify tooth and/or dental implant mobility	Osstell Beacon is indicated for use in measuring stability of implants in the oral cavity and maxillofacial region.	Same
Target Population	All dental patients	All dental patients	All patients with implants	Same
Environment of Use	Professional use/dental facility	Professional use/dental facility	Professional use/dental facility	Same
Components	The device includes **hand-held, wireless, battery driven handpiece**, single use disposable film tips, base station with USB interface for charging and data transfer, and software.	The device includes wired hand-held handpiece connected to the base station via a cable, reusable tips, power supply, USB cable for data transfer, and software.	The device is a single **hand-held wireless battery driven handpiece** with built-in graphical display. The device connects to a PC via USB for charging and includes cloud connection/ Bluetooth data communication.	Convenience only, therefore, **substantially equivalent**
Handpiece	**Wireless**	Wired	**Wireless**	Convenience only, therefore, **substantially equivalent**

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Tips	Single-use disposable film tips, discarded after single patient use. The front opening of the tip is sealed with a film membrane to prevent ingress of fluids/cross-contamination. In addition, tip has a built-in smart chip sensor to detect reuse attempt.	Reusable, autoclavable after each use	NA Tip built into handpiece. System uses single use Smartpegs.	Convenience only, enhanced infection control protocol, therefore, **substantially equivalent**
Base Station	Stores and charges handpiece battery, transfers percussion data to PC via USB. Powered by USB connection.	Powers handpiece and transfers percussion data to PC via USB. Powered by power supply.	NA	Convenience only, therefore, **substantially equivalent**
Principle of Operation	InnerView LC transfers tooth percussion data, generated by the handpiece, wirelessly to the base station, which forwards the data to the user's PC via USB. Handpiece and base station are automatically paired when the handpiece is placed into the base station. The software allows acquisition of the percussion data and returns output through the User Interface.	Periometer transfers tooth percussion data, generated by the handpiece, to the base station by a wired connection. The base station forwards the data to the user's PC via USB. The software allows acquisition of the percussion data and returns output through the User Interface.	Osstell Beacon measures the frequency response from SmartPeg directly attached to the implant or abutment. The SmartPeg is excited by an electromagnetic pulse and the measured resonance frequency is outputted as an Implant Stability Quotient (ISQ) value.	Slight difference in data transfer, through wireless vs. wired connection, does not raise different safety or efficacy questions, and performance was verified by extensive software validation, therefore, **substantially equivalent**
Mechanism of action	InnerView LC lightly percusses the buccal side of tooth/implant with a free-floating percussion probe, collects energy feedback, calculates and displays the results as energy return graph and loss coefficient, which is also the measure of tooth/implant mobility.	Periometer lightly percusses buccal side of the tooth/implant with a free-floating percussion probe, collects energy feedback, calculates and displays the results as energy return graph and loss coefficient, which is also the measure of tooth/implant mobility.	NA	Same

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Tapping activation	The force sensor in the handpiece automatically activates solenoid coil, which moves the percussion probe in a linear motion, and initiates tapping when the tip is pressed against the tooth/implant.	A button on the handpiece is pressed to manually activate solenoid coil, which moves the percussion probe in a linear motion, and initiates tapping when the tip is positioned on the tooth/implant.	NA	Automatic vs. manual tapping activation is for user convenience only and does not impact performance as verified by performance testing, therefore, **substantially equivalent**
Data acquisition	The piezo sensor in the handpiece detects the amount force absorbed by tooth/implant, the response data is converted to energy return graph and LC is calculated.	The piezo sensor in the handpiece detects the amount force absorbed by tooth/implant, the response data is converted to energy return graph and LC is calculated.	Electronics in the measurement probe detect the response signal from the detection coil in the tip and calculates the frequency of the response as ISQ.	Same
Data transfer	Data is transferred to PC via USB connection from base station, which communicates with handpiece wirelessly. The system uses Windows based software application for viewing and analyzing of the measured data. **The system has cloud connection for data storage, calculation of loss coefficient** and is not integral to the clinical functioning of the device.	Data is transferred to PC via USB connection from base station, which communicates with handpiece via wired connection. The system uses Windows based software application enabling storage and viewing of measured data.	NA. Handpiece has a built-in display. The measurement data can be transferred to cloud- based ISQ Data Manager Software via USB/PC connection for viewing and monitoring the measurement results. **The device has cloud connection**/ Bluetooth data communication.	Convenience only, software performance supported by verification/validation testing. Also reference device has a cloud connection for data transfer and monitoring, therefore, **substantially equivalent**
User Interface	PC	PC	Graphical display on Handpiece	Same
Power supply	USB interface (base station) / **rechargeable** Li-Po **battery** (handpiece)	Medical grade power supply	**Rechargeable** Li-ion **battery**	Convenience only, therefore, **substantially equivalent**
Calibration	In house prior to shipment	At point of use by user	NA	Convenience only, therefore, **substantially equivalent**

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Operation	**Device cannot operate/measure while charging**	Device is wired, and has no downtime for charging	**Device cannot operate/measure while charging**	No performance impact, same as reference device, therefore, **substantially equivalent**
Contact Force	Less than 36N	Less than 36N	NA	Same
Number of taps	5 per measurement at 4 µs increments	16 per measurement at 3.3 µs increments	NA	No performance impact, therefore, **substantially equivalent**
Output Value(s)	Energy Return Graph (ERG) and Loss Coefficient (LC)	Energy Return Graph (ERG) and Loss Coefficient (LC)	Frequency response as Implant Stability Quotient (ISQ) value	Same
Patient Contact	Percussion probe does not directly contact the tooth/implant.	Percussion probe is in direct contact with tooth/implant	NA	Improved infection control protocol, therefore**, substantially equivalent.**
Reprocessing Method	Cleaning and disinfection of handpiece and base station which cannot be autoclaved. Handpiece is used with disposable barrier sleeve. Single use disposable film tips equipped with chip sensor prevent reuse.	Cleaning and sterilization (via autoclave) of reusable handpiece and tips.	Device cannot be autoclaved, must be used with a transparent barrier sleeve. Cleaning and disinfection in the event of barrier sleeve damage Smartpeg/single patient use	Improved infection control protocol, barrier sleeve/disinfection used for reusable handpiece that cannot withstand sterilization, is consistent with reference device, therefore, **substantially equivalent**
Handpiece housing	Medical grade polycarbonate	Chrome-plated brass & nickel	ABS and PC plastic	Biocompatible materials, therefore, **substantially equivalent**
Percussion rod/probe	Stainless steel	Stainless steel	ABS plastic	Same
Tip	Medical grade polypropylene. The same material used for film membrane.	Medical grade plastic (Derlin)	ABS plastic	Biocompatible materials, therefore, **substantially equivalent**
Base Station	Medical grade polycarbonate	Stainless steel	NA	Design simplicity only, therefore, **substantially equivalent**

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VII. PERFORMANCE DATA

The InnerView LC was evaluated in accordance with FDA Guidance Document "Dental Handpieces – Premarket Notification [510(k)]" and "Reprocessing Medical Devices in Health Care Setting".

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing
The biocompatibility evaluation of the InnerView LC was conducted in accordance with the FDA's guidance document "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" and recognized consensus standards ISO 10993-1:2018" Biological evaluation of Medical Devices-Part 1: Evaluation and Testing within a Risk management Process" and ISO 7405:2018 "Dentistry- Evaluation of biocompatibility of medical devices used in dentistry". The battery of testing included cytotoxicity, sensitization, and irritation. The results demonstrate biocompatibility of the patient-contacting device components.

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical safety and EMC testing were conducted on the InnerView LC. The results demonstrate compliance with the IEC 60601-1 and IEC 60601-1-6 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation
Software verification and validation was performed, and documentation provided in accordance with the FDA's Guidance for Industry and FDA Staff "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices" and "Guidance for the Content of Premarket Submission of Management of Cyber Security in Medical Devices". The software for this device was considered an a "moderate" level of concern since a failure or latent flaw in the software could result in a minor injury or delayed treatment. The results of the software testing demonstrate that the InnerView LC performs according to specifications and functions intended. Software design and documentation comply with the IEC 62304 standard "Medical device software-software lifecycle processes".

Bench Testing
Performance testing of the InnerView LC was conducted to support substantial equivalence determination. The results demonstrate that the InnerView LC performs as well as the predicate, Periometer.

Clinical Studies
Clinical studies were not performed since the intended use and indications for use are the same and performance characteristics are equivalent.

VIII. CONCLUSION

Based on the information above, the InnerView LC is deemed substantially equivalent to the predicate device, Periometer, cleared under K072213.