



September 18, 2025

Perimetrics, Inc.
Alicia Mszyca
Sr. Director, Regulatory Affairs
8441 154th Ave. NE
Bldg. H-210
Redmond, Washington 92056

Re: K251597
Trade/Device Name: InnerView System
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories
Regulatory Class: Class I, reserved
Product Code: EKX
Dated: August 19, 2025
Received: August 19, 2025

Dear Alicia Mszyca:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, MChE, RAC, CQIA
Assistant Director

DHT1B: Division of Dental and
ENT Devices

OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

?

Please provide the device trade name(s).

?

InnerView System

Please provide your Indications for Use below.

?

The InnerView System 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 by producing two distinct outputs. InnerView's Mobility quantifies the external tooth and/or implant mobility. InnerView's NFE quantifies the internal mobility within the tooth and/or implant structure.

Please select the types of uses (select one or both, as applicable).

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

?

510(k) Summary

I. SUBMITTER

Perimetrics, Inc.
8441 154th Avenue NE
Building H, Suite 210
Redmond, WA 98052
Phone: 888-325-7218

Contact Person: Alicia Mszyca
Date: May 23, 2025

II. DEVICE

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

III. PREDICATE DEVICE

Predicate Device: InnerView LC (K232657)
No reference devices were used in this submission

IV. DEVICE DESCRIPTION

The InnerView System is an electromagnetically driven percussion system designed for dental professionals to collect percussion data of intraoral sites such as teeth and/or dental implants. The device utilizes non-destructive quantitative percussion diagnostics (QPD), a mechanics-based methodology to measure the damping capacity of a tooth and implant by applying light percussion to its buccal surface.

The InnerView System consists of a wireless handheld handpiece, a base station, single-use disposable tips, and software. A USB cable connects the base station to the user's PC. The handpiece and base station are automatically paired when the handpiece is placed in the base station. The base station also functions as a charger for the handpiece when docked. A fresh disposable tip must be attached to the handpiece before each new procedure and replaced after each patient use.

The percussion response captured by the handpiece is wirelessly transmitted to the base station, then forwarded to the PC via USB, and subsequently to the Cloud-based software for analysis and calculations. The percussion data is captured in an energy response graph (ERG), which depicts the mechanical response of the intraoral site as a function of time. InnerView proprietary software algorithms analyze the ERG data and, through the user interface, display two independent outputs: Mobility, which quantifies external mobility of the tooth or implant, and NFE, which quantifies internal mobility within the tooth or implant structure.

V. INDICATIONS FOR USE

The InnerView 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 by producing two distinct outputs. InnerView's Mobility quantifies the external mobility of the tooth and/or implant. InnerView's NFE quantifies internal mobility within the tooth or implant structure.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The InnerView System subject device is the same as the legally marketed predicate device, InnerView LC, cleared under K232657, except for an expanded indication for use.

The subject and predicate devices have the same intended use, which is for dental professionals to collect percussion data of intraoral sites, such as teeth or implants, by lightly percussing their buccal surface. Both devices have the same technological characteristics - they acquire percussive data using the same method with no changes to the type, technique, and instruments used during data acquisition. One minor difference is that the predicate uses five taps per measurement, while the subject device uses four taps. This difference does not impact data collection or clinical performance, as confirmed by verification testing, and it was implemented for user convenience to shorten the measurement time. The same type of data (energy response plotted as ERG graphs) is collected by both devices.

The primary difference is an expanded indication for the predicate device, which now, in addition to the existing Mobility output cleared under K232657, includes a new algorithm called NFE to quantify internal mobility within tooth or implant structures. InnerView System includes both Mobility and NFE.

This change does not introduce new or different questions of safety and effectiveness, as both devices use the same ERG data, the same hardware components, the same measurement technique, and clinical workflow. Both devices are tools for measuring mobility based on the identical fundamental percussive technology that produces the ERG plots. Neither device is intended to provide diagnosis.

The table below provides a detailed side-by-side comparison.

Device	Subject Device	Predicate Device	Comparison
	InnerView System	InnerView LC (K232657) ¹	
Product code	EKX	EKX	Same
Intended use	InnerView System is an electromagnetically driven system designed for dental professionals to collect percussion data of intraoral sites by lightly percussing their buccal surface.	InnerView LC is an electromagnetically driven system designed for dental professionals to collect percussion data of intraoral sites by lightly percussing their buccal surface.	Same
Indications for Use	InnerView System 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 by producing two distinct outputs. InnerView's Mobility quantifies the external mobility of the tooth/implant. InnerView's NFE quantifies internal mobility within the tooth or implant structure.	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.	See SE discussion
Intended users	Dental professionals	Dental professionals	Same
Target Population	All dental patients	All dental patients	Same
Components	The device includes a hand-held, wireless, battery-driven handpiece, single-use disposable tips, and a base station with a USB interface for charging and data transfer. A software application serves as the User Interface.	The device includes a hand-held, wireless, battery-driven handpiece, single-use disposable tips, and a base station with a USB interface for charging and data transfer. A software application serves as the User Interface.	Same
Principle of Operation	The device utilizes quantitative percussion diagnostics (QPD), an established, non-destructive mechanics-based methodology that tests the damping capacity of a tooth or implant by applying light percussion to its buccal surface. The energy returned, as a function of time, is plotted as an energy return graph (ERG), and serves as raw data for mobility calculations.	The device utilizes quantitative percussion diagnostics (QPD), an established, non-destructive mechanics-based methodology that tests the damping capacity of a tooth or implant by applying light percussion to its buccal surface. The energy returned, as a function of time, is plotted as an energy return graph (ERG), and serves as raw data for mobility calculations.	Same

Mechanism of Action	The handpiece delivers a free-floating percussion probe to the intraoral site (tooth or implant) with a consistent initial velocity that results in a maximum percussion of less than 36 N. The energy returned to the probe, normalized by the kinetic energy of the probe prior to impact versus time, is converted to an energy return graph (ERG). This serves as the raw source of data for analysis and calculations.	The handpiece delivers a free-floating percussion probe to the intraoral site (tooth or implant) with a consistent initial velocity that results in a maximum percussion of less than 36 N. The energy returned to the probe, normalized by the kinetic energy of the probe prior to impact versus time, is converted to an energy return graph (ERG). This serves as the raw source of data for analysis and calculations	Same
Indications for Use	InnerView System 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 by producing two distinct outputs. InnerView's Mobility quantifies external mobility of the tooth/implant. InnerView's NFE quantifies internal mobility within the tooth or implant structure.	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.	See SE discussion
Intended users	Dental professionals	Dental professionals	Same
Target Population	All dental patients	All dental patients	Same
Components	The device includes a hand-held, wireless, battery-driven handpiece, single-use disposable tips, and a base station with a USB interface for charging and data transfer. A software application serves as the User Interface.	The device includes a hand-held, wireless, battery-driven handpiece, single-use disposable tips, and a base station with a USB interface for charging and data transfer. A software application serves as the User Interface.	Same
Principle of Operation	The device utilizes quantitative percussion diagnostics (QPD), an established, non-destructive mechanics-based methodology that tests the damping capacity of a tooth or implant by applying light percussion to its buccal surface. The energy returned, as a function of time, is plotted as an energy return graph (ERG), and serves as raw data for mobility calculations.	The device utilizes quantitative percussion diagnostics (QPD), an established, non-destructive mechanics-based methodology that tests the damping capacity of a tooth or implant by applying light percussion to its buccal surface. The energy returned, as a function of time, is plotted as an energy return graph (ERG), and serves as raw data for mobility calculations.	Same

Mechanism of Action	The handpiece delivers a free-floating percussion probe to the intraoral site (tooth or implant) with a consistent initial velocity that results in a maximum percussion of less than 36 N. The energy returned to the probe, normalized by the kinetic energy of the probe prior to impact versus time, is converted to an energy return graph (ERG). This serves as the raw source of data for analysis and calculations.	The handpiece delivers a free-floating percussion probe to the intraoral site (tooth or implant) with a consistent initial velocity that results in a maximum percussion of less than 36 N. The energy returned to the probe, normalized by the kinetic energy of the probe prior to impact versus time, is converted to an energy return graph (ERG). This serves as the raw source of data for analysis and calculations	Same
Tapping Activation	The force sensor in the handpiece automatically activates the solenoid coil, which moves the percussion probe in a linear motion and initiates tapping when the tip is pressed against the tooth/implant.	The force sensor in the handpiece automatically activates the solenoid coil, which moves the percussion probe in a linear motion and initiates tapping when the tip is pressed against the tooth/implant.	Same
Data acquisition	The piezo sensor in the handpiece detects the amount of energy absorbed by the site. The response data is converted to an energy return graph used for analysis and calculations. Software runs mathematical algorithms to show the transmission of percussion data as a function of force and time. The results are returned through the User Interface.	The piezo sensor in the handpiece detects the amount of energy absorbed by the site. The response data is converted to an energy return graph used for analysis and calculations. Software runs mathematical algorithms to show the transmission of percussion data as a function of force and time. The results are returned through the User Interface.	Same
Data transfer	Percussion data is wirelessly transferred from the handpiece to base station, and then to the PC via USB. The device uses a Windows-based software application for viewing and analyzing the measured data. The device has a cloud connection for data storage and calculations - not integral to the clinical functioning of the device.	Percussion data is wirelessly transferred from the handpiece to base station, and then to the PC via USB. The device uses a Windows-based software application for viewing and analyzing the measured data. The device has a cloud connection for data storage and calculations - not integral to the clinical functioning of the device.	Same
Control panel	PC	PC	Same
Device output	ERG, LC (renamed in this submission as “Mobility”), and NFE	ERG and LC	See SE discussion
Mobility algorithm	Mobility is determined from the height of the ERG plot obtained from percussion data.	LC is determined from the height of the ERG plot obtained from percussion data.	Same

NFE algorithm	<p>The NFE (Normal Fit Error) is determined from the shape of ERG plot obtained from percussion data.</p> <p>The NFE calculations are based on the same percussion response (ERG) as Mobility. NFE measures the difference between the ERG and a standard bell-shaped (Gaussian) curve, which mechanistically corresponds to a structure without internal mobility). The greater the deviation of the ERG plot, the more internal mobility within tooth or implant, and a NFE value is produced.</p>	N/A	See SE discussion
Clinical workflow	To take a measurement, the patient is seated in an upright position. The user opens the InnerView app on the user's PC, selects the sites to be measured, and begins the measurement by gently pressing the handpiece against the buccal side of each selected tooth/implant. The handpiece will begin tapping upon contact with the tooth surface. The percussion output (energy return data) from each measurement is automatically captured by the software and stored in a secure cloud-based database controlled by Perimetrics. The energy returned is the raw data for calculating the device's output returned through UI.	To take a measurement, the patient is seated in an upright position. The user opens the InnerView app on the user's PC, selects the sites to be measured, and begins the measurement by gently pressing the handpiece against the buccal side of each selected tooth/implant. The handpiece will begin tapping upon contact with the tooth surface. The percussion output (energy return data) from each measurement is automatically captured by the software and stored in a secure cloud-based database controlled by Perimetrics. The energy returned is the raw data for calculating the device's output returned through UI.	Same
Power supply	USB interface (base station) / rechargeable Li-Po battery (handpiece)	USB interface (base station) / rechargeable Li-Po battery (handpiece)	Same
Tapping force	Less than 36N	Less than 36 N	Same
Number of taps	4 per measurement	5 per measurement	See SE discussion
Materials			
Handpiece	Medical grade polycarbonate	Medical grade polycarbonate	Same
Percussion Probe	Stainless steel	Stainless steel	Same
Tip	Medical grade polypropylene	Medical grade polypropylene	Same
Base Station	Medical grade polycarbonate	Medical grade polycarbonate	Same

VII. PERFORMANCE DATA

The InnerView System was evaluated in accordance with the 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 for the InnerView System 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/intracutaneous reactivity, based on the tissue contact duration of less than 24 hours.

The results demonstrate the biocompatibility of the device’s patient-contacting components.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing demonstrate compliance with the IEC 60601-1 standard for safety, and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation

Software verification and validation were conducted, and documentation provided in accordance with the FDA’s Guidance for Industry and FDA Staff “*Content of Premarket Submission for Device Software Functions*” and “*Guidance for the Content of Premarket Submission of Management of Cyber Security in Medical Devices*”.

The Documentation Level, based on the device’s intended use, design, and the risk of the device software functions, in the context of the device’s intended use, was determined to be Basic Documentation Level.

The results of the software testing demonstrate that the InnerView System performs according to the specifications and functions intended. Software design and documentation comply with the IEC 62304 standard “*Medical device software-software lifecycle processes*”.

Bench Testing

In-vitro bench testing was conducted using replica teeth and various implant structures. The results demonstrated that the InnerView System is effective in producing distinct and significantly different NFE values for tooth and implant samples with no internal mobility, compared to the tooth and implant samples with induced internal mobility.

Additional performance evaluations included human factors and usability validation, precision testing and percussion tapping comparison between the subject and predicate device.

The results support the conclusion that InnerView System is as safe and effective as the predicate device.

Clinical Testing

In-vivo clinical data was provided to demonstrate the clinical utility of the device. The results support the conclusion that the InnerView System can provide quantifiable data to measure internal mobility within the tooth and implant structure.

VIII. CONCLUSION

The InnerView System is substantially equivalent to its legally marketed predicate device, InnerView LC. The performance data included in the submission supports the safety and efficacy of the InnerView for the expanded indications.