August 16, 2024

Align Technology Ltd.
℅ Kristin Zielinski Duggan
Partner
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, District of Columbia 20004-1109

Re: K240573
Trade/Device Name: iTero Lumina™ Pro
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: Class II
Product Code: NTK, QJK
Dated: July 26, 2024
Received: July 26, 2024

Dear Kristin Zielinski Duggan:

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.

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
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240573

Device Name

iTero Lumina™ Pro

Indications for Use *(Describe)*

The iTero Lumina Pro NIRI functionality is a diagnostic aid for the detection of interproximal carious lesions above the gingiva and for monitoring the progress of such lesions.

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 – K240573
Align Technology's iTero Lumina™ Pro System

Submitter
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Date Prepared: August 14th, 2024

Name of Device: iTero Lumina™ Pro

Common or Usual Name: Caries Detector, Laser Light, Transmission

Classification Name: Laser fluorescence caries detection device

Regulation Number: 872.1745

Regulatory Class: Class II

Product Code: NTK

Predicate Device: iTero Element 5D (K193659), Align Technology Ltd.

Device Description

The **iTero Lumina Pro** is an integrated intraoral imaging system capable of capturing 3D optical impressions for CAD/CAM of dental devices, 2D color images and Near Infrared (NIR) images. Scanning cycles are employed allowing the system to quickly alternate between the three modalities, creating a virtually simultaneous capture of the 3D optical impression, 2D color and NIR images.

The principles of operation of the three modalities are briefly described hereafter.

1) **3D Optical Impression**
   During the 3D optical impression scan, 450nm (Blue) and 520nm (Green) laser light dot patterns, are operated to create the 3D model.
2) **2D Color Imaging**
   To capture the 2D color image, the intra-oral cameras are operated while the white LEDs are turned ON.
3) **NIR Imaging**
   LEDs with a wavelength of 850nm transmit light through the tooth resulting in an image that translates the teeth structure (enamel and dentin) to different brightness levels. The healthy enamel appears dark and translucent, while dentin or caries lesions appear brighter and opaque.

The NIR Imaging modality is the focus of this submission.

The **iTero Lumina Pro** consists of the following main components:

A. Scanning Wand used for intraoral scanning.
B. Wand Cradle used to hold the Scanning Wand when not in use.
C. Application Software that includes Graphical User Interface ("GUI").
D. Computer platform

The scanning wand houses electronic, mechanical, and optical components, including projectors, LEDs and cameras which enables capturing 3D impression data as well as 2D color and NIRI images. The wand body is made of Aluminum, Copolyester and Glass. When not in use, it is stored in the Wand Cradle.

The iTero Lumina Pro features proprietary software that can be installed on the various configurations of the computer platform. The software is designed to manage the GUI, control the scanning process, display the scanned images, and connect to the stored patient data, including scanned data for display or export.

The iTero Lumina scanning wand is designed to be used with a single-use, non-sterile, disposable, wand barrier sleeve. The only patient-contacting materials are those contained within the wand barrier sleeve.

Intended Use / Indications for Use

The iTero Lumina Pro NIRI functionality is a diagnostic aid for the detection of interproximal carious lesions above the gingiva and for monitoring the progress of such lesions.

Summary of Technological Characteristics

NIR imaging is the technological principle for both the subject and predicate devices. For both the predicate and the subject device, the NIR LEDs create an 850nm wavelength illumination that transmits through a tooth and is captured by cameras. The NIR Image translates the teeth structure (enamel and dentin) to different brightness levels. The healthy enamel appears dark and translucent, while dentin or caries lesions appear brighter and opaque.

At a high level, the subject and predicate devices are based on the following same technological elements. The iTero Lumina Pro and the iTero Element 5D systems include similar hardware and software components designed to obtain and display NIR images for a dentist's review.

Both system's scanning wand comprise three different light sources, which are capable of capturing 3D optical impressions for CAD/CAM of dental devices, 2D color images and Near Infrared (NIR) images. In addition, the light sources operate in a substantially equivalent manner, given that they utilize periodical light source activation (i.e., alternating ON / OFF depending on the required modality: 3D optical impression, 2D color imaging and NIR imaging).

Both devices employ a similar cross contamination prevention strategy in which the user is required to apply a new disposable wand barrier sleeve before each use. The scanning process is also similar in that the user selects the scanning features, places the wand tip slightly above the subject's teeth, initiates the scan by using the control buttons and moves the scanning wand above the area which is required to be scanned.

The subject and predicate devices differ in the number of cameras and sensors and the optical pathway of the emitted lights. While the predicate device encompasses two (2) NIR LEDs and one (1) camera, the subject device has multiple NIR LEDs and cameras and thus can simultaneously acquire NIR images from several angles. In contrast, the predicate device requires more manipulation during scanning in order to capture images from several angles.

The predicate device displays the NIR images both in real time and offline, while the subject device presents the NIR images only upon completion of the scan. Despite this minor difference, both devices meet the clinical need of evaluating the NIR images to aid in diagnosis and monitoring the progress of potential interproximal caries. Clinicians do not typically evaluate the NIR images for aiding in diagnosis during scanning, but rather the evaluation occurs at the end of the scan, making this difference inconsequential.

Both the subject and predicate devices share the same indications for use.

The table below provides a comparison of the fundamental technological characteristics of the iTero Lumina Pro System and those of its predicate device.

	iTero Lumina Pro K240573 (Subject device)	**iTero Element 5D K193659 (Predicate device)**
Indications for Use/ Intended Use	The iTero Lumina Pro NIRI functionality is a diagnostic aid for the detection of interproximal carious lesions above the gingiva and for monitoring the progress of such lesions.	The iTero Element 5D is a diagnostic aid for the detection of interproximal caries lesions above the gingiva and for monitoring the progress of such lesions.
User Population	Dentist	Dentist
Design	Hand-held device	Hand-held device
Main Device Components	Hand-held device with USB, cable, software and computer.	Hand-held device with USB, cable, software and computer. Alternatively, software is installed on a personal computer that meets performance parameters defined by the company.

	iTero Lumina Pro K240573 (Subject device)	iTero Element 5D K193659 (Predicate device)
Functional Principle	Transillumination: Based on the principle that the tooth enamel is translucent to NIR light hence its image appears dark, while dentin and caries lesions scatter NIR light hence their image appears bright.	Transillumination: Based on the principle that the tooth enamel is translucent to NIR light hence its image appears dark, while dentin and caries lesions scatter NIR light hence their image appears bright.
NIRI Light Source	Infrared light emitting diode (LED)s are used to generate exactly 850nm wavelength which are detected by the CMOS sensor.	Infrared light emitting diode (LED)s are used to generate exactly 850nm wavelength which are detected by the CMOS sensor.
Installation	The computer-based installation enables the customer to install and update the software.	The computer-based installation enables the customer to install and update the software.
Power Source	The power supply of the wand is USB-15V	The power supply of the wand is USB-15V
Software	The software consists of a product firmware and a computer-based software, which controls: - Display of pictures - stores/-saves the pictures - Live stream controlling of camera functions, such as brightness and contrast.	The software consists of a product firmware and a computer-based software, which controls: - Display of pictures - Stores/ saves the pictures - Live stream controlling of camera functions, such as brightness and contrast.
Standards with which the Device Complies	IEC 60601-1	IEC 60601-1
Compatibility	USB connection	USB connection
Cross contamination control	A single use, disposable, wand barrier sleeve.	A single use, disposable, wand barrier sleeve.
Wavelength	850 nm	850 nm

	iTero Lumina Pro K240573 (Subject device)	iTero Element 5D K193659 (Predicate device)
Illumination Type	Pulsed Illumination – method of illumination that consists of periodical light source activation. i.e. alternating ON(pulse)/OFF states.	Pulsed Illumination – method of illumination that consists of periodical light source activation. i.e. alternating ON(pulse)/OFF states.

Performance Data

The company has performed bench testing to support the substantial equivalence of the iTero Lumina Pro to the predicate device.

For the Near Infrared Imaging (NIR) functionality, key performance attributes tested included: Field of View, Image Sharpness and Depth of Field, illumination Power, Wavelength and Spectral Bandwidth, Specular Reflection Suppression, and Signal to Noise Ratio. All testing showed similar performance to the predicate system.

Testing for the Lumina Pro wand barrier sleeve testing met requirements for dental barriers regulated under 21 C.F.R §878.4370 and demonstrated equivalent performance as the predicate device wand barrier sleeve. The testing included the following:

- Material testing of the iTero Lumina Pro wand barrier components was conducted in accordance with ASTM D882-12 (tensile testing), ASTM D1004-13 (tear resistance), ASTM F1342/F1342M-05 and ASTM D2582-16 (puncture resistance), ASTM F1670/F1670M-17a (penetration resistance), and additional internally derived test protocols.
- Finished assembly testing of the wand barrier sleeve including Microbial Ingress Testing, Pull testing in accordance with ASTM D3330/D3330M-04(18), and additional internally derived test protocols.

Basic Safety and Electromagnetic Compatibility (EMC) testing confirmed the iTero Lumina Pro complies with IEC 60601-1 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance), IEC 80601-2-60 (Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment), IEC 60601-1-6 (Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability), IEC 62366-1 (Application of Usability Engineering to Medical Devices), IEC 60601-1-2 (Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and Tests), FDA Guidance on Electromagnetic Compatibility (EMC) of Medical Devices issued in June 2022 and, FDA Guidance on Radio Frequency Wireless Technology in Medical Devices issued in August 2013, along with lamps and laser safety standards including IEC 62471, Photobiological safety of lamps and lamp systems and IEC 60825-1, Safety of laser products – Part 1: Equipment classification, requirements and user's guide.

The iTero Lumina Pro software application has been designed and developed according to IEC 62304 (Medical Device Software Life-Cycle Processes) and FDA Guidance on Content of Premarket Submissions for Device Software Functions issued in June 2023.

Cybersecurity is ensured by compliance with the requirements of UL ANSI 2900-1 (Standard for Safety, Standard for Software Cybersecurity Network-Connectable Products, Part 1: General Requirements), UL ANSI 2900-2-1 (Standard for Safety Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems), and the FDA Guidance on Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions issued in September 2023.

Patient contacting components were shown to be biocompatible for their intended use per the recognized consensus standards in the ISO 10993-series. The device was found to be reliably cleaned through validated cleaning methods, including intermediate disinfection level validation of the wand and cradle, that comply with the requirements of ANSI/AAMI ST98:2022 standard and FDA Guidance on Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued in March 2015 and Appendix E which was updated in June 2017.

Conclusions

The **iTero Lumina Pro System** is as safe and effective as the predicate device, the **iTero Element 5D**. The **iTero Lumina Pro System** has the same intended use and indications for use, and similar technological characteristics, and principles of operation as its predicate device. The minor differences in design do not alter the intended clinical use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the **iTero Lumina Pro System** and its predicate devices raise no new questions of safety or effectiveness. Performance data demonstrate that the **iTero Lumina Pro System** is as safe and effective as the **iTero Element 5D**. Thus, the **iTero Lumina Pro System** is substantially equivalent.