July 2, 2026

Align Technology , Ltd.
Aviva Touati
Director Regulatory Affairs
1 Yitzhak Rabin Rd.
Petach Tikva, 4925110
ISRAEL

Re: K261847
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
Dated: June 1, 2026
Received: June 3, 2026

Dear Aviva Touati:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
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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.

510(k) Number *(if known)*
K261847

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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K261847 - 510(k) SUMMARY

Submitter
Align Technology Ltd.
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Phone: +972544622662
email: atouati@aligntech.com
Contact Person: Aviva Touati
Date Prepared: July 1st, 2026

Name of Device: iTero Lumina Pro™

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

Classification Name: Laser fluorescence caries detection device

Regulation Number and Class: 21 CFR 872.1745, Class II

Product Code: NTK

Predicate Device: iTero Lumina Pro™ (K240573), Align Technology Ltd.

Device Description

The **modified 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 first two modalities describe device functions that are subject of regulation 872.3661 which is exempt from 510(k). The NIR Imaging modality is the focus of this submission.

The **modified 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 **modified 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 modified 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.

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

The **modified iTero Lumina Pro** and the predicate device consist of the same hardware components including the same hand-held scanning unit and computer platform and involve the same principles of operation. The Substantial Equivalence Comparison Table provides a comparison of the fundamental technological characteristics of the **modified iTero Lumina Pro** System and those of its predicate device.

Both systems include the same optical components and integrate three optical modalities into one system: 3D digital impressions, 2D color images and NIR images. The devices use similar optical cycles and same illumination power.

The software in both systems consists of a product firmware and a computer-based software. The software in both systems is designed to; manage the graphical user interface (GUI) through which users interact with the system, select scanning modes, and manage scanned data (including sending or storing it), to control the scanning wand according to the selected scanning mode and, to connect to stored data for display or export. The scanning process remains unchanged in terms of hardware operation, optical paths used for acquiring NIR images, and scanning workflow.

The devices include similar software components designed to obtain and display NIR images for a professional dental health care provider's review. The NIRI modality workflow and user interaction remain consistent compared to the predicate device, performing the same sequence of tasks as previously defined (e.g., patient setup via Rx (prescription) Form filling, scanning, data acquisition, and displayed output (image) review / visualization).

The software modifications introduced in the subject device are intended for enhancement of the software performance, to further refine existing processing capabilities in order to optimize the displayed output based on the user positioning of the loupe while maintaining and adjusting the artifacts reduction feature. The modified software supports the same software functionalities as the predicate device. The software modifications affect only the post-processing step.

The differences in the **modified iTero Lumina Pro**'s software do not alter the underlying scanning technology or system's intended use. The **modified iTero Lumina Pro** software enhancements do not alter the core functionality or clinical workflow of the device.

Both the subject and predicate devices are designed to be used with a substantially equivalent, single-use Wand Barrier Sleeve. Both barrier sleeves function as a physical barrier covering the wand tip and wand body to reduce the risk of cross-contamination while preserving the ability to obtain high-quality images. The subject and predicate Wand Barrier Sleeves consist of a rigid portion covering the wand tip and a flexible polyethylene sheath portion covering the wand body and overlapping the rigid sleeve, including coverage of the proximal portion of the tip, resulting in continuous barrier integrity.

The subject and predicate Wand Barrier Sleeves differ in (1) configuration as provided to the user, and (2) optical window and adhesive foam materials. These differences were evaluated and determined not to raise new or different questions of safety or effectiveness when compared to the predicate device and were verified using established, well-characterized bench testing methodologies, as described below.

Accordingly, the technological characteristics of the subject device and predicate are substantially equivalent.

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

Modified Feature / Characteristic	Modified iTero Lumina Pro K261847	iTero Lumina Pro K240573 (Predicate device)
Main Device Components	Hand-held device with USB, cable, software and computer.	Hand-held device with USB, cable, software and computer.
Software	The software consists of a product firmware and a computer-based software, which controls the acquisition, selection and display of dental images, and allows interaction of the user with the application-	The software consists of a product firmware and a computer-based software, which controls the acquisition, selection and display of dental images, and allows interaction of the user with the application-
Cross contamination control	A single use, disposable, wand barrier sleeve composed of a rigid sleeve that covers the tip of the handpiece and a flexible PE sheath that covers the handpiece body.	A single use, disposable, wand barrier sleeve composed of a rigid sleeve that covers the tip of the handpiece adhered to a flexible PE sheath that covers the handpiece body.
Patient-Contacting Materials and Contact Type	Mucosal (Oral) Direct: • PE: 70% HDPE – Purell GA7760, 30% LDPE – Purell PE 1840H; • Inorganic borosilicate crown optical glass, B270 • LDPE film FL9106 2 mil thickness Mucosal (Oral) Indirect: 3M Transfer Adhesive 1524	Mucosal (Oral) Direct: • PE: 70% HDPE – Purell GA7760, 30% LDPE – Purell PE 1840H; • Cast polymethyl methacrylate (PMMA) • LDPE film FL9106 2 mil thickness Mucosal (Oral) Indirect: • Polyethylene Foam Tape MED 6654R White Polyethylene Foam Tape MED 5696R White
Single-Unit Packaging Configuration	Packaged as a single assembled unit in a LDPE zip bag. Each 20 packed single units are packed in a shelf box. Shipping box configuration includes 2 or 8 shelf boxes.	Rigid sleeve packaged in the same LDPE zip bag as the predicate; sheath packaged separately within protective paper and polyethylene covers. Each 20 packed single units of Sheathes and of Rigid Sleeves are packed in the

Modified Feature / Characteristic	Modified iTero Lumina Pro K261847	iTero Lumina Pro K240573 (Predicate device)
		same shelf box as the predicate. The same Shipping boxes are used as the predicate are used for transportation.
Modified Feature / Characteristic	**Modified iTero Lumina Pro (Subject device)**	**iTero Lumina Pro K240573 (Predicate device)**
Main Device Components	Hand-held device with USB, cable, software and computer.	Hand-held device with USB, cable, software and computer.
Software	The software consists of a product firmware and a computer-based software, which controls the acquisition, selection and display of dental images, and allows interaction of the user with the application-	The software consists of a product firmware and a computer-based software, which controls the acquisition, selection and display of dental images, and allows interaction of the user with the application-
Cross contamination control	A single use, disposable, wand barrier sleeve composed of a rigid sleeve that covers the tip of the handpiece and a flexible PE sheath that covers the handpiece body.	A single use, disposable, wand barrier sleeve composed of a rigid sleeve that covers the tip of the handpiece adhered to a flexible PE sheath that covers the handpiece body.
Single-Unit Packaging Configuration	Packaged as a single assembled unit in a LDPE zip bag. Each 20 packed single units are packed in a shelf box. Shipping box configuration includes 2 or 8 shelf boxes.	Rigid sleeve packaged in the same LDPE zip bag as the predicate; sheath packaged separately within protective paper and polyethylene covers. Each 20 packed single units of Sheathes and of Rigid Sleeves are packed in the same shelf box as the predicate. The same Shipping boxes are used as the predicate are used for transportation.

Performance Data

To support the substantial equivalence of the modified iTero Lumina Pro to the predicate device, the company has performed bench testing following well-established bench and software testing methods which were based on FDA-recognized voluntary consensus standard and on methods previously used for the clearance of the predicate device, consistent with FDA's Special 510(k) guidance.

For the Near Infrared Imaging (NIR) functionality, key performance attributes tested included: software testing, NIR image sharpness and NIR image 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.

Patient contacting components were shown to be biocompatible for their intended use per the recognized consensus standards in the ISO 10993-series.

Conclusions

The **modified iTero Lumina Pro** System is substantially equivalent to the predicate device, the **iTero Lumina Pro** System. The **modified iTero Lumina Pro** System has the same intended use and indications for use. Both systems operate based on the same fundamental principles of operation and have substantially equivalent technological characteristics. The minor technological differences between the subject and predicate devices were evaluated using well-established, validated testing methodologies. These evaluations demonstrated that the differences do not raise new or different questions of safety or effectiveness when compared to the predicate device. Performance data supporting that the **modified iTero Lumina Pro** system is substantially equivalent to the predicate device, as previously summarized.

Based on this assessment, the **modified iTero Lumina Pro** system is therefore substantially equivalent to the iTero Lumina Pro system cleared under 510(k) number K240573.