March 20, 2020

Align Technology, Inc.
% Angela Frederickson
Director of Government Affairs, RA, QA - Americas
Hogan Lovells US LLP
1601 Wewatta St #900
Denver, Colorado 80202

Re: K193659
Trade/Device Name: iTero Element 5D
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: Class II
Product Code: NTK
Dated: March 11, 2020
Received: March 11, 2020

Dear Angela Frederickson:

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020 *See PRA Statement below*

510(k) Number *(if known)*

K193659

Device Name

iTero Element 5D

Indications for Use *(Describe)*

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.

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 K193659

iTero Element 5D

Align Technology, Inc.

Submitter

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Contact

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Date Prepared: March 11, 2020

Name of Device: iTero Element 5D

Classification Name: Laser fluorescence caries detection device

Regulatory Class: Class II

Product Code: NTK

Regulation Number: 21 CFR 872.1745

Predicate Devices:

CamX Triton HD Proxi Head (K172007)

Device Description

The iTero Element 5D is an integrated intraoral imaging system capable of 3D confocal optical impressions for CAD/CAM of dental devices, which also captures 2D color images and Near Infrared (NIR) images.

The iTero Element 5D consists of a scanning wand, wand cradle, single-use, disposable, 5D barrier sleeve, iTero Element 5D Sleeve (protective sleeve), software (including GUI), and a computer hardware platform that is offered in two configurations:

1. Laptop Configuration, where the GUI is presented on a customer-provided PC Laptop Touchscreen;

2. Wheel Stand Configuration where the GUI is presented on a display panel that is mounted on a wheel stand base unit.

The scanning wand and software, including the GUI, are common to both configurations.

The scanning wand which has 3 imaging capabilities: 1) 3D confocal optical impression, 2) 2D color imaging and 3) near infrared imaging (NIRI), is designed to be used with a single-use, disposable, scanning wand barrier sleeve ("5D barrier sleeve") during scans and a protective sleeve during storage. At the beginning of every scan, the single-use, disposable, 5D barrier sleeve is placed on the scanning wand's head. The wand tip is placed slightly above the patient's teeth and the scan is initiated. At the end of the scan, proprietary imaging software converts the scan into an image that is simultaneously presented alongside the 2D color images and NIR images on the GUI display. The 3D confocal optical impression and 2D color images assist in orientation by providing an enhanced view of the scanned teeth, thus helping the user identify which areas (i.e. occlusal direction/angles) to view as NIR images. The 2D color image displays a close-up view of the teeth while the NIR Image translates the teeth structure (enamel and dentin) to different brightness levels.

Intended Use / Indications for Use

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.

Summary of Technological Characteristics

The iTero Element 5D System is similar in its technological features to its predicate device, the CamX Triton HD Proxi Head system. Both systems are indicated for use as a diagnostic aid for the detection of interproximal caries lesions above the gingiva and for monitoring the progress of such lesions. Both systems consist of similar types of components and involve similar principles of operation. The iTero Element 5D and the CamX Triton HD Proxi Head system both include hardware and software components. Both systems are designed for obtaining real time NIR images. Both systems are comprised of a handheld device with a USB cable connected to a computer, on which the proprietary software is installed. Both systems encompass the technology to display color images on a monitor that are obtained by an intraoral camera. The iTero Element 5D encompass a single handpiece and camera head that enables simultaneous capturing of 3D confocal optical impressions, 2D color images and NIR images, compared to its predicate device, where a different interchangeable head must be used depending on the imaging modality desired. This feature of the iTero Element 5D has no effect on safety or effectiveness but rather allows for greater convenience for the user.

The iTero Element 5D handpiece is designed to be covered during the procedure by a custom-made, single-use, disposable, 5D barrier sleeve. The 5D barrier sleeve is designed to enable the user to obtain images of the required quality while alleviating the risk of cross-contamination. The proposed predicate device uses a single-use, flexible, disposal handpiece cover to achieve the same objectives. The 5D barrier sleeve and predicate handpiece cover are both physical barriers designed to alleviate the potential risk of cross-contamination while preserving the ability to obtain high-quality images.

The 5D barrier sleeve is comprised of three (3) key components; 1) rigid sleeve 2) polyethylene sheath 3) adhesive tape. The rigid sleeve component of the 5D barrier sleeve is designed to protect the optical window from damage while preserving the quality of the images captured during the scan.

Comparatively, the predicate device utilizes an autoclavable distance spacer, positioned on top of the covered handpiece to maintain a constant distance between the lens window and the patient's teeth. The handpiece, including the interchangeable camera head, is covered by a 510(k) cleared flexible hygienic cover during use. Performance data, further described in this submission, demonstrate that the complete 5D barrier sleeve and its key components provide similar image quality preservation, mechanical properties, and cross-contamination protection as the cleared hygienic cover of the proposed predicate. As such, the differences between the 5D barrier sleeve and the predicate hygienic cover do not affect safety or effectiveness of the subject device.

Based on this assessment, the iTero Element 5D has similar technological characteristics relative to the predicate. Evaluation of the minor technological differences between the iTero Element 5D and its predicate device do not raise new issues of safety or effectiveness. A table comparing the key features of the subject and predicate devices is provided below.

Comparison Table, Summarizing the Similarities and Differences between the iTero Element 5D and its Predicate Device

Descriptive Information	iTero Element 5D, NIRI Functionality (subject device)	CamX Triton HD Proxi Head System K172007 (predicate)
Indications for Use	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.	The CamX Triton HD Proxi Head is a diagnostic aid for the detection of interproximal caries lesions above the gingiva and for monitoring the progress of such lesions.
Design	Hand-held device	Hand-held device
Main Device Components	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.	Hand-held device with USB, cable and software. The software is installed on a personal computer that meets performance parameters defined by the company.
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	Two Infrared light emitting diode (LED)s are used to generate exactly 850nm wavelength which are detected by the CMOS sensor.	Two Infrared light emitting diode (LED)s are used to generate exactly 850nm wavelength which are detected by the CMOS sensor.

Descriptive Information	iTero Element 5D, NIRI Functionality (subject device)	CamX Triton HD Proxi Head System K172007 (predicate)
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-5V
Compatibility	USB connection	USB connection
Compliance to Standards	IEC 60601-1	IEC 60601-1
Cross contamination control	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	Handpiece is covered with a flexible PE sheath. Spacer that is autoclaved is placed on the sheath at the tip of the handpiece
Available configurations	Two configurations: 1) Laptop Configuration 2) Wheel Stand Configuration	One configuration: Handpiece and propriety software. The handpiece can be connected via USB to a computer (customer provided)
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 is a computer based software, which controls: - Display of pictures - Store / save the pictures - Live stream Controlling of camera functions such as brightness and contrast
Intended Users	Dentist	Dentist
Wavelength	850 nm	850 nm
Irradiance (Power Density)	Max. average irradiance is 3 mW/cm^2 at 1.5mm distance	Max. irradiance is 3.4 mW/cm^2 at a distance of 8 mm (spacer)
Illumination Type	Pulsed Illumination – method of illumination that consists of periodical light source activation. i.e. alternating ON(pulse)/OFF states.	Continuous Illumination - method of illumination in which the source is activated continuously.

Non-Clinical Performance Testing

The following nonclinical performance testing has been conducted to support the substantial equivalence of the iTero Element 5D to its predicate device. In all instances, the iTero Element 5D functioned in a substantially equivalent manner relative to the predicate.

- Comparison testing of the image quality of the subject device and the predicate was conducted to demonstrate that the following parameters were comparable between the two devices:

- Image sharpness at all working distances of the scanning wand
- Field Of View (measured in horizontal and vertical axes in mm)
- Signal to Noise ratio (measured in dB)

- System level testing of NIRI functionality was conducted in order to evaluate performance requirements for the image sharpness, specular reflection, signal to noise ratio, field of view, depth of field, centroid wavelength, spectral width, illumination power and working distance related to the NIR imaging.

- Barrier Testing

    - Material testing of the 5D barrier sleeve 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 mechanical test protocols.
    - Finished assembly testing of the full barrier including Microbial Ingress Testing and Peel Adhesion testing in accordance with ASTM D3330/D3330M-04(18).
    - Barrier tests plan was designed to be consistent with testing utilized to support clearance of dental barriers and sleeves regulated under 21 C.F.R §878.4370, FDA product code PEM.

- Biocompatibility testing of the patient-contacting components of the device was performed in accordance with ISO 10993-5 and ISO 10993-10.

- Reprocessing: Cleaning and intermediate level disinfection validations were conducted to substantiate that the iTero Element 5D scanning wand and cradle can be reprocessed in accordance with the Spaulding classification for semi-critical devices.

- Electromagnetic Compatibility and Electrical Safety for the two configurations (laptop and wheel stand) was performed. These tests include electrical safety per IEC 60601-1 ver. 3.1, EMC per IEC 60601-1-2, 4th edition, photobiological safety per IEC 62471:2006, laser safety per IEC 60825-1:2014 and electrical dental equipment per IEC 80601-2-60: 2012.

Clinical performance testing

Clinical performance testing was not conducted/provided.

Conclusions

Based on similarities in indications for use and technological characteristics together with results of non-clinical performance testing, iTero Element 5D is substantially equivalent to the CamX Triton HD Proxi Head system.