September 9, 2025

DGNCT, LLC
% Kelliann Payne
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
PHILADELPHIA, PA 19103

Re: K251072
Trade/Device Name: Segmentron Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: April 7, 2025
Received: August 11, 2025

Dear Kelliann Payne:

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,

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
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OHT8: Office of Radiological Health
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251072

Device Name
Segmentron Viewer

Indications for Use *(Describe)*
Segmentron Viewer is a software product intended for processing and manipulating maxillofacial radiographic images. Segmentron Viewer allows users to perform the following functions:

1. Viewing patient images (provides tools for image processing and viewing functions);
2. Reading and 3D visualization of CBCT images;
3. Generating editable 3D STL files (for educational purposes only).

The device is indicated for use by medical professionals (such as dentists and radiologists), in patients 14 years and older with permanent teeth.

Segmentron Viewer is a web application. It can be used in a network environment.

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.

510(k) Summary

DGNCT LLC'S Segmentron Viewer (K251072)

Submitter

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Contact Person: Anastasya Melnikov

Date Prepared: September 9, 2025

Name of Device: Segmentron Viewer

Device Classification: CFR 892.2050 Medical image management and processing system

Regulatory Class: II

Product Code: QIH

Predicate Device: Ez3D-i/E3 device (K231757) (Ewoosoft Co., Ltd.)

Device Description

Segmentron Viewer is a semi-automated software as a medical device (SaMD) for dental image processing and management. The device's main function is to perform automated analysis of maxillofacial Cone Beam Computed Tomography (CBCT) images uploaded by the user, which consists of applying artificial neural network models (AI) to such images to obtain automatically generated 3D segmentations of teeth and anatomy. The user is able to edit these segmentations. The device also provides functions for enhancement and 3D visualization of the images. It additionally enables uploading, saving, and sharing CBCT images for the clinician's ease of use.

Segmentron Viewer identifies each tooth and tooth pulp present in the upper and the lower jaw (as shown on the input scan), numbers them, and segments them. Similarly, the device identifies each of eight maxillofacial anatomy structures in a CBCT scan, and segments them. The software facilitates navigation through the images for detailed evaluation and produces multi-planar reconstruction (MPR) views of each segmented object. The device generates a segmentation report from the input CBCT scan, for the healthcare provider's (HCP) use to further evaluate a patient's teeth and anatomy.

Intended Use / Indications for Use

Segmentron Viewer is a software product intended for processing and manipulating maxillofacial radiographic images. Segmentron Viewer allows users to perform the following functions:

1. Viewing patient images (provides tools for image processing and viewing functions);
2. Reading and 3D visualization of CBCT images;
3. Generating editable 3D STL files (for educational purposes only).

The device is indicated for use by medical professionals (such as dentists and radiologists), in patients 14 years and older with permanent teeth.

Segmentron Viewer is a web application. It can be used in a network environment.

IFU comparison: Both the subject and predicate devices are intended as tools for dental professionals to use in processing maxillofacial radiographic imaging. The differences in specific indications for use – including Segmentron Viewer's narrower range of input imaging sources and image formats – do not raise different questions of safety or effectiveness, as the fundamental clinical use is the same.

Summary of Technological Characteristics

Segmentron Viewer has the same general intended use and similar indications for use, technological characteristics, and principles of operation as the previously cleared predicate device, Ez3D-i /E3 (K231757). Both devices are based on the same fundamental scientific technology and principles of operation: Both are software-only, AI-based devices that utilize a supervised machine learning algorithm to provide comparable tools for processing and manipulation of maxillofacial radiographic images. At a high level, the two devices are based on the following same technological elements:

- Both devices segment the teeth and anatomical structures in a CBCT image.
- Both devices offer tools to export data to interface with other software.
- Both devices offer features such as MPR and 3D image analysis, enabling the viewing and evaluation of radiographic images in similar ways.
- Both devices are DICOM compatible, ensuring similar usability and integration capabilities.
- Both devices support the generation of reports to document findings and enhance clinical workflow.

Moreover, the primary differences in technology between the two devices do not raise different questions of safety and effectiveness. Performance test data demonstrate Segmentron Viewer's ability to safely and effectively achieve its intended use and its various individual functions, and support its substantial equivalence to the predicate.

The predicate supports a broader range of imaging modalities than Segmentron Viewer. However, both products focus on providing accurate visualization and segmentation/labeling of dental and maxillofacial images. The differences in specific visualization and processing functions do not raise different questions of safety or effectiveness. The additional features of the subject device (such as segmentation of pulp in addition to teeth) serve only to enhance the flexibility of its analysis. Similarly, features of the predicate that are absent in Segmentron Viewer serve only to supplement the core functionality of the predicate without altering the general intended use which Segmentron shares. A table comparing the key features of the subject and predicate devices is provided below.

Performance Data

DGNCT LLC evaluated the performance of Segmentron Viewer in four retrospective standalone validation studies, comparing the software's segmentation and labeling performance against reference standards ("ground truth"). The primary objective in each study was to assess the agreement between the algorithm's output and the reference standard.

U.S. board-certified radiologists established a reference standard for each CBCT image, using manual segmentation (for the segmentation studies) or annotation (for the labeling study). The same CBCT

images were then analyzed using the Segmentron Viewer. For the segmentation studies, Dice Coefficient (DSC) was used as the primary endpoint to evaluate segmentation agreement between the algorithm and the reference standard. For the labeling study, overall accuracy was used to evaluate labeling agreement. The dataset used for the studies included CBCT scans sourced from a variety of geographic regions and demographics. The studies are outlined below.

1. *Tooth Segmentation:* This study assessed the ability of Segmentron Viewer to segment and number teeth in 126 CBCT scans of permanent teeth. Across all teeth, Segmentron demonstrated strong segmentation agreement with the reference standard, as evidenced by the Dice Coefficient (primary endpoint) exceeding the pre-defined performance goal (PG) with a result of 0.96 (95% CI: 0.95, 0.96; $p < 0.0001$), as well as success on the pre-defined secondary endpoints.

2. *Pulp Segmentation:* This study assessed the ability of Segmentron Viewer to segment dental pulp in 43 CBCT scans. Across the pulp of all teeth, Segmentron demonstrated strong segmentation agreement with the reference standard, as evidenced by Dice Coefficient (primary endpoint) = 0.88 (95% CI: 0.87, 0.89; $p < 0.0001$) – exceeding the pre-defined PG – and success on the secondary endpoints.

3. *Anatomy Segmentation* : This study assessed the ability of Segmentron Viewer to segment 8 anatomical structures in 56 CBCT scans. Across all anatomical structures, Segmentron demonstrated strong segmentation agreement with the reference standard. The primary endpoint was met, as the Dice Coefficients for each anatomical region exceeded their respective pre-defined PGs.

4. *Labeling Performance:* This study aimed to validate the accuracy of labels automatically generated by the device for teeth, anatomical structures, and pulp on 40 CBCT scans from the larger validation dataset. Across all teeth, pulp, and anatomical structures in all CBCT scans, Segmentron Viewer achieved a labeling accuracy of 100%, demonstrating strong concordance between the labels automatically generated by the device and those determined by an expert radiologist.

Conclusion

Segmentron Viewer is as safe and effective as the predicate device, Ez3D-i (K231757). The subject device has the same intended use and similar indications for use, technological characteristics, and principles of operation. The minor differences in indications do not alter the intended clinical use of the device as compared to its predicate, nor do they affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between Segmentron Viewer and its predicate raise no new questions of safety or effectiveness. Performance data demonstrates that the subject device functions as intended and further supports substantial equivalence.

Criteria	Subject Device: Segmentron Viewer	Predicate Device: Ez3D-i /E3 (K231757)	Comparison
Regulation #	21 CFR 892.2050	21 CFR 892.2050	
Device	Automated radiological image processing software	Automated radiological image processing software	Same
Product Code	QIH	QIH	Same
Intended Use/ Indications for Use	Segmentron Viewer is a software product intended for processing and manipulating maxillofacial radiographic images. Segmentron Viewer allows users to perform the following functions: 1. Viewing patient images (provides tools for image processing and viewing functions); 2. Reading and 3D visualization of CBCT images; 3. Generating editable 3D STL files (for educational purposes only). The device is indicated for use by medical professionals (such as dentists and radiologists), in patients 14 years and older with permanent teeth. Segmentron Viewer is a web application. It can be used in a network environment.	Ez3D-i/E3 is dental imaging software that is intended to provide diagnostic tools for maxillofacial radiographic imaging. These tools are available to view and interpret a series of DICOM compliant dental radiology images and are meant to be used by trained medical professionals such as radiologist and dentist. Ez3D-i/E3 is intended for use as software to load, view and save DICOM images from CT, panorama, cephalometric and intraoral imaging equipment and to provide 3D visualization, 2D analysis, in various MPR (Multi-Planar Reconstruction) functions	Same intended use. The minor differences in indications for use do not raise different questions of safety or effectiveness or alter the fundamental clinical purpose.
Functions and Capabilities	• View and save images from CBCT scanners • Image measurement • Multi-Planar Reconstruction (MPR) functions • 3D image viewing and reformation • Rendering functions, e.g., MPR and 3D rendering (visualization), 3D zoom • Image segmentation • Export capabilities • Generates reports • Manage and add objects • Image manipulation (e.g., magnify, hue, brightness) • Image annotation • Cloud-based storage	• View and save images from CT, panorama, cephalometric and intraoral imaging equipment • Image measurement • Multi-Planar Reconstruction (MPR) functions • 2D image viewing and analysis • 3D image viewing and reformation (including canal drawing) • Rendering functions, e.g., Volume Rendering, MIP, miniIP, X-ray, and 3D zoom • Image Segmentation • Transfer images • Generates reports • Manage and add objects, color maps, fine tuning • Image manipulation (e.g., magnify, hue, brightness) • Image annotation • Implant simulation tools for treatment planning • Bone density profiling	Both are AI-based, software-only devices providing tools for viewing/evaluating pre-existing maxillofacial radiographic images. The differences in specific functions do not raise different questions.
Algorithm	Supervised machine learning	Supervised machine learning	Same
Image Format	DICOM	DICOM	Same
Configuration	Web application	Desktop application	Similar