May 23, 2025

Ewoosoft Co., Ltd
℅ Hyeonguk Kang
Regulatory Affairs Team Manager
801-Ho, Vatechnetworks Bldg., 13, Samsung 1-Ro 2-Gil
HWASEONG-SI, GYEONGGIDO 18449
SOUTH KOREA

Re: K250005
Trade/Device Name: Clever One
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: April 18, 2025
Received: April 21, 2025

Dear Hyeonguk Kang:

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

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250005

Device Name
Clever One

Indications for Use *(Describe)*
Clever One is dental imaging software that is intended to provide tools for supporting diagnosis and treatment. These tools enable end users to view and interpret a series of DICOM compliant medical images and are intended for use by trained medical professionals. Clever One allows users to load, view, and save DICOM images from CT, panoramic, cephalometric, intraoral, and other imaging equipment. It also provides functionalities such as 2D viewing, 2D analysis, 3D visualization, 3D analysis.

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

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. **Date**: May 23, 2025

2. **Applicant / Submitter**

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3. **Subject Device:**

- Trade/Device Name: Clever One
- Regulation Number: 21 CFR 892.2050
- Regulation Name: Medical Image Management and Processing System
- Regulatory Class: Class II
- Product Code: QIH

4. **Predicate Device:**

- Manufacturer: Ewoosoft Co., Ltd.
- Trade/Device Name: EzDent-i
- 510k Number: K241114
- Regulation Number: 21 CFR 892.2050
- Regulation Name: Medical Image Management and Processing System
- Regulatory Class: Class II
- Product Code: LLZ

- Manufacturer: Ewoosoft Co., Ltd.
- Trade/Device Name: Ez3D-i
- 510k Number: K231757
- Regulation Number: 21 CFR 892.2050
- Regulation Name: Automated Radiological Image Processing Software
- Regulatory Class: Class II
- Product Code: QIH

6. Device Description:

Clever One is a dental imaging software designed to acquire, process, view, edit, and analyze medical images for supporting diagnostic and preoperative planning purposes. It supports standard DICOM formats for 2D and 3D image files and enables advanced imaging functionalities for enhanced diagnostic accuracy.

The software provides a range of features, including:
- 2D Imaging: Loading, editing, and viewing 2D dental images in standard formats (e.g., DICOM, JPG, BMP).
- 3D Imaging: Visualization and reconstruction of 3D CT images, including multi-planar views (MPR) and volume rendering.
- Preoperative Planning: Implant position simulation, canal drawing, and bone density analysis to support treatment planning.
- Data Interoperability: Facilitates data transfer and storage using DICOM-compliant workflows, ensuring compatibility with third-party systems and imaging devices.

The software interfaces with dental imaging equipment, such as CT, panoramic, cephalometric, and intraoral X-ray systems, as well as intraoral cameras, for image acquisition. It is designed for use in network environments, allowing users to upload and download clinical diagnostic images and patient data for enhanced collaboration and efficient patient management.

7. Indication for use:

Clever One is dental imaging software that is intended to provide tools for supporting diagnosis and treatment.
These tools enable end users to view and interpret a series of DICOM compliant medical images and are intended for use by trained medical professionals. Clever One allows users to load, view, and save DICOM images from CT, panoramic, cephalometric, intraoral, and other imaging equipment. It also provides functionalities such as 2D viewing, 2D analysis, 3D visualization, 3D analysis.

8. Intended Patient Population

Our product has no clinical diagnostic or treatment functions and its main purpose is visualizing data. All contents shown in the software are visualized information of numerical values acquired from acquisition equipment and visualization results only assist end-users in patient counseling, diagnosis, and treatment planning. Users can adjust the visualization settings according to content viewed by the user. All diagnosis and treatment decisions made are solely up to the user. The 3D tooth segmentation function is limited to adult subjects with permanent teeth.

9. Substantial Equivalence:

	Subject Device	Equivalent Device	Equivalent Device
Device name	Clever One v1.0	EzDent-i v3.4	Ez3D-i v5.5
510K number	-	K241114	K231757
Manufacturer	Ewoosoft	Ewoosoft	Ewoosoft
Indications for use	Clever One is dental imaging software that is intended to provide tools for supporting diagnosis and treatment. These tools enable end users to view and interpret a series of DICOM compliant medical images and are intended for use by trained medical professionals. Clever One allows users to load, view, and save DICOM images from CT, panoramic, cephalometric, intraoral, and other imaging equipment. It also provides functionalities such as 2D viewing, 2D analysis, 3D visualization, 3D analysis.	EzDent-i 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. EzDent-i is intended for use as software to acquire, view and save 2D image files, load DICOM project files from panorama, cephalometric, and intra-oral imaging equipment.	Ez3D-i 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 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.
Technology/Principle of Operation	Clever One is a dental imaging software designed to acquire, process, view, edit, and analyze medical images for supporting diagnostic and preoperative planning	EzDent-i is a device that provides various features to acquire, transfer, edit, display, store, and perform digital processing of medical images. EzDent-i is a patient &	Ez3D-i v5.5 is 3D viewing software for dental CT images in DICOM format with a host of useful functions including MPR, 2-dimensional analysis and 3-

	purposes. It supports standard DICOM formats for 2D and 3D image files and enables advanced imaging functionalities for enhanced diagnostic accuracy. The software provides a range of features, including: - 2D Imaging: Loading, editing, and viewing 2D dental images in standard formats (e.g., DICOM, JPG, BMP). - 3D Imaging: Visualization and reconstruction of 3D CT images, including multi-planar views (MPR) and volume rendering. - Preoperative Planning: Implant position simulation, canal drawing, and bone density analysis to support treatment planning. - Data Interoperability: Facilitates data transfer and storage using DICOM-compliant workflows, ensuring compatibility with third-party systems and imaging devices.	image management software specifically for digital dental radiography. It also provides server/client model so that the users upload and download clinical diagnostic images and patient information from any workstations in the network environment. EzDent-i supports general image formats such as JPG and BMP for 2D image viewing as well as DICOM format. EzDent-i supports the acquisition of dental images by interfacing with OpenCV library to import the intra-oral camera images. It also supports the acquisition of CT/Panoramic/Cephalo/Intra-Oral Sensor images by interfacing with X-ray capture software.	dimensional image reformation. It provides advanced simulation functions such as Implant Simulation, Drawing Canal, and Implant Environ Bone Density, etc. for the benefit of effective doctor and patient communication and precise treatment planning.

	The software interfaces with dental imaging equipment, such as CT, panoramic, cephalometric, and intraoral X-ray systems, as well as intraoral cameras, for image acquisition. It is designed for use in network environments, allowing users to upload and download clinical diagnostic images and patient data for enhanced collaboration and efficient patient management.		
Platform	IBM-compatible PC or PC network	IBM-compatible PC or PC network	IBM-compatible PC or PC network
Operating System	Microsoft Window 10 or higher	Microsoft Windows 10,11	Microsoft Window 10 or higher
User Interface	Mouse, Keyboard	Mouse, Keyboard	Mouse, Keyboard
Image Input Sources	Images can be scanned, loaded from digital cameras or card readers, or imported from a radiographic imaging device	Images can be scanned, loaded from digital cameras or card readers, or imported from a radiographic imaging device	Images can be scanned, loaded from digital cameras or card readers, or imported from a radiographic imaging device
32 bit / 64 bit	64 bit	32 / 64 bit	64 bit
Image format	DICOM	DICOM	DICOM
Patient Database Compatibility	SQL	SQL	SQL
Includes Image Measurement tools	Length, Multi Length, Angle, Multi Angle, Circle, ROI/Area, Volume, Profile	Linear distance, angle	Length, Multi Length, Angle, Multi Angle, Circle, ROI/Area, Volume, Profile
Image viewing	Full, side by side, gallery, thumbnail	Full, side by side, gallery, thumbnail	Full, side by side, gallery, thumbnail

Image manipulation	Grayscale, invert, emboss, brightness, contrast, gamma, sharpen, median, despeckle, hue, saturation, equalize, flip, mirror, masking, rotate, magnify, annotation, cephalometric tracing, ceph growth, projections, implant simulations, film view, zooming, whitening, nerve canal tracing, memo	Brightness, contrast, sharpness, inverse, film view, rotate, zooming, whitening, nerve canal tracing, memo	Grayscale, invert, emboss, brightness, contrast, gamma, sharpen, median, despeckle, hue, saturation, equalize, flip, mirror, masking, rotate, magnify, annotation, cephalometric tracing, ceph growth, projections, implant simulations
Implant module	Generic implant libraries	Generic implant libraries	Generic implant libraries
3D imaging capability	Clever One can view, transfer and process 3D radiographs. Furthermore, it supports Smart Click, Smart Clipping, Implant Simulation and Canal Draw.	Includes interface to 3D imaging software, Ez3D-i. EzDent-i imaging software does not view, transfer or process 3D radiographs.	Ez3D-I can view, transfer and process 3D radiographs. Furthermore, it supports Smart Click, Smart Clipping, Implant Simulation and Canal Draw.
Image annotation	Test, paint, ellipse, pointer, select, draw, magnify, line, rectangle, polygon, ruler, protractor, smile library, smudge, brush, redeye reduction, select region, copy / paste	Text, paint, ellipse, pointer, select, draw, magnify, line, rectangle, polygon, ruler, protractor, smile library, smudge, brush, redeye reduction, select region, copy / paste	Test, paint, ellipse, pointer, select, draw, magnify, line, rectangle, polygon, ruler, protractor, smile library, smudge, brush, redeye reduction, select region, copy / paste
Distribution of Installation File for Upgrade	USB, EzUpdater	EzUpdater	USB, EzUpdater
Customer Support	Manufacturer website, phone number, and e-mail information provided.	Manufacturer website, phone number, and e-mail information provided.	Manufacturer website, phone number, and e-mail information provided.

Dose Information Display	File information, Dose indicator (if applicable)	File information, Dose indicator (if applicable)	File information, Dose indicator (if applicable)
Report Management	Create, open, view, edit, delete	Create, open, view, edit, delete	Create, open, view, edit, delete
Pre-integrated PMS	Clever Dent, Weclever	Clever Dent, Weclever	Clever Dent, Weclever
Send E-mail	Send e-mail, attachment, compress to zip file, signature, convert report to, converted image to, patient information anonymization	Send e-mail, attachment, compress to zip file, signature, convert report to, converted image to, patient information anonymization	Send e-mail, attachment, compress to zip file, signature, convert report to, converted image to, patient information anonymization

The subject device, Clever One, is a software product designed to combine the functionality of two predicate devices, EzDent-i and Ez3D-i. EzDent-i provides 2D imaging capabilities, while Ez3D-i offers 3D imaging capabilities. Clever One integrates the technologies of these two devices to support both 2D and 3D imaging, resulting in a unified platform for medical imaging.

1. **Technological Comparison**:
   Clever One adopts the same technological principles as EzDent-i and Ez3D-i, utilizing DICOM image formats and digital image input sources. The combined technology enables Clever One to provide both 2D and 3D imaging functionalities, which align directly with the features offered by the predicate devices. All major functionalities—including bone density analysis and implant simulation—are identical to those of the predicate devices EzDent-I and Ez3D-I.

2. **Principle of Operation**:
   The operation of Clever One is substantially equivalent to EzDent-i and Ez3D-i. Clever One inherits the 2D imaging capabilities from EzDent-i and the 3D imaging capabilities from Ez3D-i without introducing new principles of operation.

3. **Software and Platform**:
   All devices, including Clever One, operate on a Windows-based platform using Windows 10 as the operating system. The integration of functionalities does not alter the fundamental platform compatibility.

4. **User Interface and Functional Enhancements**:
   The user interface of Clever One integrates and enhances the graphical interfaces of EzDent-i and Ez3D-i to support 2D and 3D imaging in a seamless manner. This enhancement does not introduce new risks or functionalities beyond those already established by the predicates.

5. **Safety and Effectiveness**:
   The combined functionalities of Clever One do not raise new questions regarding safety or effectiveness. The system builds upon validated features of EzDent-i and Ez3D-i, ensuring that the overall safety profile remains consistent with the predicates.

Conclusion:
Clever One is substantially equivalent to the predicate devices EzDent-i (K241114) and Ez3D-i (K231757) in terms of technology, principle of operation, platform, and functional capabilities. The integration of 2D and 3D imaging does not introduce new technological characteristics that would require additional validation beyond that conducted for the predicate devices.

10. Technological Characteristics:

Clever One is a software device that does not contact the patient, nor does it control any life sustaining devices. Results produced by the software's diagnostic, treatment planning and simulation tools are dependent on the interpretation of trained and licensed radiologists, clinicians and referring physicians as an adjunctive to standard radiology practices for diagnosis.

11. Performance Data:

SW verification/validation and the measurement accuracy test were conducted to establish the performance, functionality and reliability characteristics of the subject devices. The device passed all of the tests based on pre-determined Pass/Fail criteria.
The subject device incorporates a new platform that features network and cloud connectivity. In accordance with the FDA's guidance document, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions," comprehensive cybersecurity risk management and verification and validation activities were conducted. The results of these cybersecurity assessments, the supporting documentation, and the cybersecurity management plan are included in this premarket submission.

12. Conclusion:

The subject device is substantially equivalent in the areas of technical characteristics, general function, application, and indications for use. The new device does not introduce a fundamentally new scientific technology, and the device has been validated through system level test. Therefore, we conclude that the subject device described in this submission is substantially equivalent to the predicate device.