



July 23, 2025

Infomed Software, S.L.  
% Juan Tezak  
Consultant  
Compliance 4 Devices  
118 W Prive Cr.  
DELRAY BEACH, FL 33445

Re: K250716  
Trade/Device Name: IMAGE ONE  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Medical Image Management And Processing System  
Regulatory Class: Class II  
Product Code: LLZ  
Dated: June 26, 2025  
Received: June 26, 2025

Dear Juan Tezak:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A large, light blue 'FDA' watermark is visible in the background. Overlaid on it is a handwritten signature in black ink that reads 'Lu Jiang'.

Lu Jiang, Ph.D.  
Assistant Director  
Diagnostic X-Ray Systems Team  
DHT8B: Division of Radiological Imaging  
Devices and Electronic Products  
OHT8: Office of Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K250716

Device Name

IMAGE ONE

Indications for Use (Describe)

IMAGE ONE is a dental imaging software that is intended to provide viewer and image processing tools for maxillofacial radiographic images. 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.

IMAGE ONE is intended for use as software to acquire, view, and save 2D and 3D image files, to load DICOM project files from panorama, cephalometric, and intra-oral imaging equipment, and to provide 3D visualization and 2D 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(k) Summary

### K250716

Prepared July 15, 2025

#### I) Applicant

|           |                                                          |
|-----------|----------------------------------------------------------|
| Submitter | Infomed Software, S.L.                                   |
| Address   | Vía Augusta 158 – 4th floor.<br>08006. Barcelona, Spain. |
| Contact   | Mrs. Iris López                                          |
| Telephone | +34 934 144 340                                          |
| E-mail    | iris.lopez@grupoinfomed.es                               |

#### II) Device

|                     |                                                |
|---------------------|------------------------------------------------|
| Trade Name          | IMAGE ONE                                      |
| Common Name         | Picture Archiving and Communications System    |
| Classification Name | Medical image management and processing system |
| Regulation Number   | 892.2050                                       |
| Product Code        | LLZ                                            |

#### III) Predicate Device

|                     |                                                |
|---------------------|------------------------------------------------|
| 510(k) Number       | K230468                                        |
| Applicant           | Ewoosoft Co., Ltd.                             |
| Trade Name          | EzDent Web                                     |
| Classification Name | Medical image management and processing system |
| Regulation Number   | 892.2050                                       |

#### IV) Indication For Use

IMAGE ONE is a dental imaging software that is intended to provide viewer and image processing tools for maxillofacial radiographic images. 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.

IMAGE ONE is intended for use as software to acquire, view, and save 2D and 3D image files, to load DICOM project files from panorama, cephalometric, and intra-oral imaging equipment, and to provide 3D visualization and 2D analysis.

#### V) Device Description

IMAGE ONE software is an image management software which runs in a browser containing a user interface that allows the dentist to access and display patients' images or videos that have been taken during the course of a clinical practice.

IMAGE ONE is cloud-based Software which runs in a web browser with no access to hardware devices.

The only way that IMAGE ONE may retrieve files is by requesting them from the file system of the Operating System.

There are two scenarios involving the abovementioned files:

- In the first one, the files may have been generated in the past by an external system, in which case IMAGE ONE allows the user to import and catalog them immediately.
- The other one is when the files do not exist yet and are going to be generated during a clinical procedure by an external system. The user can request IMAGE ONE to wait for the user to complete an external acquisition process before importing and cataloging the files automatically.

IMAGE ONE software supports image and video standards commonly used in dentistry to date. These include X-ray radiographic images in PNG, JPEG, or BMP format, 3D models in STL format obtained from intraoral scans, intraoral video in MP4 format, and computed tomography images in DICOM format.

In addition to its image management functions, the software also offers through its user interface a visualization enhancement function (zoom and filters functions) for X-ray radiographic images in either PNG, JPEG, or BMP format. An additional distance measuring function is also included but strictly restricted to X-ray radiographic images in format PNG, JPEG, or BMP displaying a calibrator.

## VI) Comparison of Technological Characteristics

| Characteristics                   | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Predicate Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Device name                       | IMAGE ONE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | EzDent Web                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 510K number                       | K250716                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | K230468                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Manufacture                       | Infomed Software, S.L.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Ewoosoft Co., Ltd                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Indications for use               | <p>IMAGE ONE is a dental imaging software that is intended to provide viewer and image processing tools for maxillofacial radiographic images. 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.</p> <p>IMAGE ONE is intended for use as software to acquire, view, and save 2D and 3D image files, to load DICOM project files from panorama, cephalometric, and intra-oral imaging equipment, and to provide 3D visualization and 2D analysis.</p> | <p>EzDent Web is a dental imaging software that is intended to provide viewer and image processing tools for maxillofacial radiographic images. 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.</p> <p>EzDent Web is intended for use as software to acquire, view, and save 2D and 3D image files, to load DICOM project files from panorama, cephalometric, and intra-oral imaging equipment, and to provide 3D visualization and 2D analysis.</p> |
| Technology/Principle of Operation | <p>The visualization enhancement tools of the IMAGE ONE software, allow for better visualization of a given tooth structure. They include:</p> <ul style="list-style-type: none"> <li>- zoom function (maximum magnification X10)</li> <li>- and filter functions (brightness, contrast, color inversion, color, smoothing,</li> </ul>                                                                                                                                                                                                                                                            | <p>EzDent Web is a device that provides various features to acquire, transfer, edit, display, store, and perform digital processing of medical images. EzDent Web is a patient &amp; 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</p>                                                                                                                                                                                                                           |

| Characteristics                  | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Predicate Device                                                                                                                                                                                   |
|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Device name                      | IMAGE ONE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | EzDent Web                                                                                                                                                                                         |
| 510K number                      | K250716                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | K230468                                                                                                                                                                                            |
|                                  | <p>sharpness and relief).</p> <p>About the measurement of dental structures on 2D images of X-ray radiographs; measurements can only be performed on 2D images containing a caliper of known size. IMAGE ONE cannot perform measurements on 2D images obtained from computed tomography (CT) or computed tomography (CAT) scans, as the caliper is not directly present within the image. In these specific cases, the caliper information is encoded within the DICOM metadata format of the image. The IMAGEONE software cannot retrieve such information from the DICOM metadata.</p> <p>Therefore, the use of the IMAGEONE software for measurement purposes is indicated only for intraoral and extraoral radiographs captured on flat films and digital sensors. The images produced are two-dimensional shadow plots, representing the absorption of the incident X-ray beam as it penetrates the various structures before exposing the image receptor.</p> <p>The caliper or caliper must be present directly on the image. It may take the form of a caliper or an object of known size. To achieve sufficient resolution, it is not recommended that the caliper be less than 50 mm in length.</p> | <p>patient information from any workstations in the network environment.</p> <p>EzDent Web supports general image formats such as JPG and BMP for 2D,3D image viewing as well as DICOM format.</p> |
| Platform                         | Google Chrome Version 100 or higher                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | IBM-compatible PC or PC network                                                                                                                                                                    |
| Operating System                 | Microsoft Windows 10 or higher                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Microsoft Windows 10 or Higher                                                                                                                                                                     |
| User Interface                   | No public interfaces defined                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Mouse, Keyboard                                                                                                                                                                                    |
| Image Input Sources              | X-ray images in PNG, JPEG, or BMP format, 3D models in STL format obtained from intraoral scans, intraoral video in MP4 format, and CT images in DICOM format.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Images can be scanned, loaded from digital cameras or card readers, or imported from a radiographic imaging device                                                                                 |
| Image format                     | Radiographic images in PNG, JPEG, or BMP format, 3D models in STL format obtained from intraoral scans, intraoral video in MP4 format, and computed tomography images in DICOM format                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | DICOM, JPG, BMP                                                                                                                                                                                    |
| Patient Database Compatibility   | SQL server for image management                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | SQL                                                                                                                                                                                                |
| Includes Image Measurement tools | Linear distance, angle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Linear distance, Angle, Profile                                                                                                                                                                    |
| Image viewing                    | Full, gallery, thumbnail                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Full, side by side, gallery, thumbnail                                                                                                                                                             |

| Characteristics    | Subject Device                                                                                                                                          | Predicate Device                                                                                                                          |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| Device name        | IMAGE ONE                                                                                                                                               | EzDent Web                                                                                                                                |
| 510K number        | K250716                                                                                                                                                 | K230468                                                                                                                                   |
| Image manipulation | Zoom function (maximum enhancement X10), and filter functions including brightness, contrast, invert colours, colour, softening, sharpening and relief. | Brightness, contrast, sharpness, inverse, film view, rotate, zooming, draw canal, memo, implant simulations                               |
| Implant module     | N/A                                                                                                                                                     | Generic implant libraries                                                                                                                 |
| Image annotation   | Text, paint, ellipse, pointer, select, draw, line, rectangle, polygon.                                                                                  | Text, paint, ellipse, pointer, select, draw, magnify, line, rectangle, polygon, ruler, protractor, reduction, select region, copy / paste |

IMAGE ONE and its predicate EzDent Web are very similar products in terms of their intended use, composition and effectiveness in providing image viewing and processing tools for maxillofacial radiographic imaging.

#### VII) Technological Characteristics

IMAGE ONE is a software device that does not contact the patient, nor does it control any life sustaining devices.

- The IMAGE ONE software allows the viewing of dental X-ray, 3D models in STL format obtained from intraoral exploration, intraoral video in MP4 format and CT images in DICOM format, taken with the purpose of helping diagnosis and preventing and/or treating diseases of the mouth.
- The human anatomical areas covered by the IMAGE ONE software are limited to the oral cavity, including the oral vestibule and its bone structure, namely the jaw, maxilla, and palatine bones.
- The display enhancement functions (zoom and filter functions) can be used for X-ray images in PNG, JPEG or BMP format.
- The distance measurement function is restricted to 2D X-ray images in PNG, JPEG or BMP format, showing a calibrator.
- Use of both the display enhancement and the distance measurement features gives professional users (dentists) preliminary information about the patient's dental health.
- The distance measurement function of the IMAGE ONE software is not to be used in preparing for any kind of dental surgery, including dental implants or orthognathic surgery.
- The distance measuring function of IMAGE ONE software shall not be used for orthodontic treatment planning and/or diagnosis.

#### VIII) Performance Data

SW verification/validation and the measurement accuracy test were conducted to establish the performance, functionality and reliability characteristics of the modified devices. The device passed all of the tests based on pre-determined Pass/Fail criteria.

#### IX) Conclusion

The subject device is substantially equivalent in the areas of technical characteristics, general function, application and indications of use to the predicate device K230468.