August 4, 2026

3diemme Srl
℅ Alesandro Avis
Quality and Regulatory Supervisor
Via Risorgimento 9
CANTÙ, 21047
ITALY

Re: K253902
Trade/Device Name: RealGUIDE
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: December 23, 2025
Received: December 23, 2025

Dear Alesandro Avis:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FDA Digitally signed by GABRIELA M. for RODAL -S

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253902

Please provide the device trade name(s).

RealGUIDE

Please provide your Indications for Use below.

RealGUIDE is a stand-alone software indicated for the preparation of patient specific treatment planning by professional user and, in particular, it must be used by dental clinician, general practitioner (DDS) dentist, or specialist such as, a Periodontist or Oral Sur-geon. The software is indicated for use on patients that require dental implant placement planning, prosthesis modelling and endodontic treatments connected to the endosseous dental implant placement. RealGUIDE is, in further detail, indicated for:
- Viewing in 2D/3D patient images and processing them (DICOM or STL), including volume editing and measurement
- Segmenting bone, nerve canal and teeth
- Virtually positioning dental implants
- Designing templates for endosseous dental implant guided placement
- Modelling reconstructive devices, such as bone grafts and grids
- Designing dental prosthetics, such as crown, bridges and dentures
- Saving dental surgery template's or prostheses' design to file

RealGUIDE software allows for endosseous dental implant surgical guide and prosthetic component file creation (*.STL) for the user to further process with specific CAD systems before export to validated manufacturing centers or to the point of care. Manufacturing at the point of care requires a validated process using CAM equipment (additive manufacturing system, including software and associated tooling) and compatible material (biocompatible and sterilizable).
The software is not intended to perform automatic diagnosis and to control the manufacture of devices.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

1 Submitter

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2 Subject device

Proprietary Name: RealGUIDE
Classification Name: Medical Image Management And Processing System
Common Name: Automated Radiological Image Processing Software
Regulation: 892.2050
Primary Product Code: QIH
Additional Product Code(s): LLZ

3 Predicate device

Name of Device: 3Diemme RealGUIDE
Manufacturer: 3Diemme
K Number: K173041
Product Code: LLZ

Reference Device #1:
Name of Device: Relu Creator
Manufacturer: Relu BV
K Number: K233925
Product Code: QIH

Reference Device #2:
Name of Device: Atomica Planner
Manufacturer: Atomica Technology, Inc.
K Number: K230012
Product Code: LLZ

4 Device description

RealGUIDE is a stand-alone software that supports all the common 3D medical imaging functionalities used by professional doctors to support their diagnosis. It includes various Volume and IsoSurface rendering, segmentation tools, masking and sculpting, MPR, 2D and 3D measurement and analysis tools. Since 2D imaging is still an important feature, it is possible to switch with a single click to a 2D view, use an even more sophisticated MPR view or switch back to the 3D view.
RealGUIDE is characterized by its intuitive user interface, 2D, MPR and 3D imaging, prime image quality and extensive visualization options, fast image rendering, measurement and analysis tools, and easy integrated reporting. The software is integrating all the surface and volume modelling tools necessary to integrate the diagnostic and virtual planning functions to any CAD/CAM and rapid prototyping system for further processing and manufacturing.
The output format of the software is a STL file, mainly focused on dental surgery. A list of the possible devices that can be modelled with the software is reported below:

- Surgical guides for endosseous dental implants
- Bone graft models for mandible/maxilla regenerative procedures
- Dental and maxillofacial prosthesis

RealGUIDE Software is available for digital download or via web browser. When used on a local computer, the software is installed on the user's machine and run on its hardware. When used via browser, the user accesses the version available for all users, installed on the server.

Each desktop user has to install a version of RealGUIDE while browser users can access the version available on the server through their preferred internet application. A brief example of user access is given in the following diagram.

5 Indications for use

RealGUIDE is a stand-alone software indicated for the preparation of patient specific treatment planning by professional user and, in particular, it must be used by dental clinician, general practitioner (DDS) dentist, or specialist such as, a Periodontist or Oral Sur-geon. The software is indicated for use on patients that require dental implant placement planning, prosthesis modelling and endodontic treatments connected to the endosseous dental implant placement. RealGUIDE is, in further detail, indicated for:

- Viewing in 2D/3D patient images and processing them (DICOM or STL), including volume editing and measurement
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RealGUIDE software allows for endosseous dental implant surgical guide and prosthetic component file creation (*.STL) for the user to further process with specific CAD systems before export to validated manufacturing centers or to the point of care. Manufacturing at the point of care requires a validated process using CAM equipment (additive manufacturing system, including software and associated tooling) and compatible material (biocompatible and sterilizable).
The software is not intended to perform automatic diagnosis and to control the manufacture of devices.

6 Comparison of technological characteristics with the predicate device

The software functions available in RealGUIDE are designed to give the user tools

- to visualize DICOM images for diagnostic purpose. Based on the image's characteristics, the user will base his clinical decisions. In this circumstance, RealGUIDE is only capable of visualizing the images, giving the user the ability to set filers and remove unwanted parts of it from the field.
- To virtually place implants within the DICOM images, to plan the dental guided surgery to be performed in a later stage. Given the fact that RealGUIDE is intended to drive clinical management only, thus aid in diagnosis and treatment, the information it provides is necessary for the next treatment intervention. Implant position and surgery are always the responsibility of the qualified professional carrying out the surgery. RealGUIDE does not provide diagnosis.
- To virtually design the surgical guide for dental guided surgery. The characteristics of the guide are always based on the previous implant planning and on the anatomical features detected with the diagnostic imaging systems.
- To virtually model the prothesis. Crown or dental prosthesis modelling is always based on previous implant planning.

The device under evaluation is an update of the predicate device, with two major characteristics:

1. Creation of a specific version of RealGUIDE WEB to be installed on a server, functionally equivalent to the existing desktop version, and to be accessed by the user from a web browser.
2. Introduction of AI/ML based algorithms to limited functions, currently only available in manual mode.

The AI/ML algorithms introduced are locked and the device cannot learn from the data it is provided with, once it has been released to the market.

A comparison with the predicate device and reference devices shows that the technological characteristics of the devices are similar.

Feature	RealGUIDE	3Diemme RealGUIDE	Relu Creator	Atomica Planner
510(k) number	-	K173041	K233925	K230012
DICOM 2D/3D reconstruction	Yes	Yes	Yes	Yes
Panoramic image reconstruction	Yes	Yes	No	
Segmentation of anatomy and dentures (nerve canals, bone, crown, teeth)	Yes	Yes	Yes	Yes
Import and matching STL files	Yes	Yes	Yes	Yes
Implant planning from library	Yes	Yes	No	Yes
Teeth setup	Yes	Yes	No	Yes
Surgical guides design	Yes	Yes	No	Yes
Model design	Yes	Yes	Yes	Yes
Prosthesis design	Yes	Yes	No	No
Freeform modelling & design	Yes	Yes	No	Yes
Virtual articulator	Yes	Yes	No	No
AI/ML enabled functionality	Yes	No	Yes	Yes
PC version	Yes	Yes	No	Yes
Mac version	Yes	Yes	No	No
Mobile version	Yes	Yes	No	No
WEB version	Yes	No	Yes	No

Overall, the technological characteristics of the subject device are the same of the predicate and reference devices. The new features of the subject device are equivalent to the ones already available on reference devices such as Relu (WEB version) and Atomica (AI/ML functions).

7 Performance data

Non-clinical data submitted or referenced to demonstrate substantial equivalence included:

- Software verification & validation results
- AI/ML validation

The software under evaluation is the subsequent update of the previously marketed version of RealGUIDE (K152078), being considered as predicate device.

Testing demonstrates the implemented functions perform as intended, and differences between the Device and the predicates do not raise additional concerns with the Device's safety and effectiveness.

8 Conclusion

For the purpose of demonstrating the substantial equivalence of RealGUIDE (subject device) to already cleared and marketed devices, the following aspects have been considered.

- **Indications for use:** no substantial difference in intended user, medical application and patient population.
- **Principle of operation:** to perform image processing, virtual dental implant positioning, surgical guide design and prosthetic modelling the software works on a proprietary algorithm using commonly available libraries and self-developed software code. With no changes to the software architecture to implement the new function, the subject device now has two different ways (manual and automatic) of performing a function that was already available. Thus, no substantial change to the operating principle has been made
- **Software features:** the main functions of the subject device, with respect to the predicate devices have remained unchanged. The addition of the web based application to access the server installation of RealGUIDE does not represent a change affecting safety and effectiveness of the device. All AI/ML based functions were already available in RealGUIDE, to be performed only manually.
- **Primary product Code (QIH):** the change is administrative, considering the Product Code is belonging to the same regulations. No change in risk classification. The difference in product code reflect the presence of AI/ML enabled functions that have been introduced to the Radiological Image Processing System (LLZ) previously cleared, and considered as Predicate Device.

Based on the comparison of intended use, indications, principle of operations, features, technical data and the test results, the RealGUIDE software is thought to be substantially equivalent in safety and effectiveness to the predicate and reference devices listed.