December 20, 2018

3DIEMME Ltd.
% Lara Luzak
Senior Regulatory Specialist
Registar Corp
144 Research Drive
HAMPTON, VA 23666

Re: K173041
Trade/Device Name: 3DIEMME RealGUIDE
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 9, 2018
Received: November 13, 2018

Dear Lara Luzak:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173041

Device Name
3DIEMME RealGUIDE

Indications for Use *(Describe)*

PC/MAC version:

The RealGUIDE software is intended for the following uses:

1. Support to the diagnosis for trained professionals. The input DICOM files acquired by a CT/CBCT scanner are not modified in any way but they are showed to the doctor through the classical imaging and volume rendering techniques. It is a stand-alone product. No information of the patient is modified, all the parameters used for the image processing are read from the DICOM file itself. Neither automatic diagnosis is made, nor automatic disease detection is performed. This software is not connected to any medical instrumentation and it doesn't control any medical or energy supplying device. The user imports DICOM data coming from any CT/CBCT imaging device and the software enables him to view the Patient exam in different multi-planar 2D images and easily reconstruct the 3D volume for an immediate visualization of bone structures and surrounding tissues.
2. Virtual oral and maxillofacial surgery planning. Doctors can plan virtual implants and surgeries on 2D/3D reconstructions and export the projects in open or proprietary format for further processing. The user can choose different implant models (for example dental implants models) from a library provided by the Manufacturers and simulate the positioning in the Patient reconstructed volume (this operation is called "virtual plan")
3. Dental/maxillofacial surgical guides and prosthetic modelling. The virtual plan is used to design a surgical guide that is used by the doctor to drive the surgery drills according to the planned implants direction and depth. This surgical guide can be manufactured by any 3D printer working from STL files. The user can also design the patient prosthesis (typically a denture) with the surface and volume free-form tools implemented in the software. The result is exported in STL format for 3D printing or CAD/CAM technologies.

Mobile version:

The RealGUIDE software APP is intended for the following uses:

1. Projects visualization and editing. The input PROJECT files, pre-processed with the RealGUIDE desktop version, are used by trained professionals to evaluate the implants projects, edit them and share them with other colleagues through the cloud, as well as for a more effective Patient treatment communication.

The RealGUIDE APP version is NOT INTENDED for managing a 3D diagnosis starting from DICOM images, due to the mobile devices screen resolution limitations. For this reason, the APP is not reading directly the DICOM files but only pre-processed project files, exported through the cloud by the RealGUIDE desktop version.

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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1 Submitter

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2 Subject device

Proprietary Name: 3DIEMME RealGUIDE
Classification Name: System, Image Processing, Radiological
Regulation: 892.2050
Product Code: LLZ

There have been no prior submissions for the subject device.

3 Predicate device

Name of Device: Implant Studio™ 2015-1
Manufacturer: 3Shape Medical A/S
K Number: K152078
Product Code: LLZ

This predicate device has not been subject to a design-related recall.

Reference Device #1:
Name of Device: Simplant 2011
Manufacturer: Materialise Dental NV
K Number: K110300
Product Code: LLZ

This reference device has not been subject to a design-related recall.

Reference Device #2:
Name of Device: Codiagnostix Implant Planning Software
Manufacturer: Straumann USA
K Number: K130724
Product Code: LLZ

This reference device has not been subject to a design-related recall.

Reference Device #3:
Name of Device: Maven Pro
Manufacturer: nSequence
K Number: K130242
Product Code: LLZ

This reference device has not been subject to a design-related recall.

4 Device description

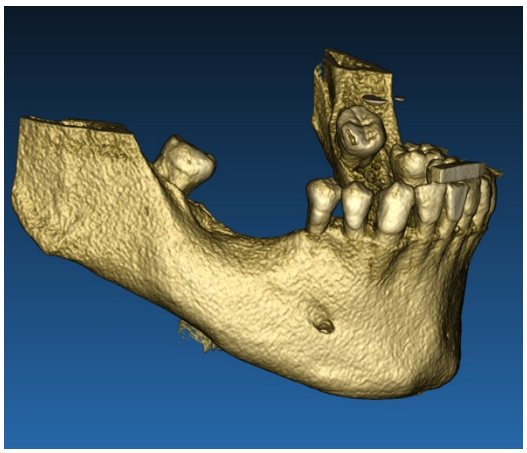
RealGUIDE Graphic Station is a fully-featured 3D imaging application in medicine. Its unique open architecture and modular framework make customization and integration options trivial. RealGUIDE Graphic Station is meant to be a multiplatform application, running on PC, MAC and mobile devices (not provided by 3DIEMME). The RealGUIDE software is capable of displaying oral/maxillofacial radiology. The user is then able to navigate through different views, segmented analysis (cross sections), and 3D perspective. In addition, the user is able to simulate various objects within the radiograph for the purpose of treatment planning.
Once treatment planning and visual simulation is complete, users can generate reports and simulated images for the purpose of evaluation and diagnosis, as well as perform a surgical guide and prosthesis modelling, to be exported in STL format for the manufacturing with any RP or CAD/CAM machine.
The output format of the software is a STL file, mainly focused on dental, maxillofacial and orthognatic surgery. A list of the possible devices that can be modelled with the software is reported below:

- Surgical guides for dental implants and surgical screws planning
- Bone cutting and bone reduction guides for maxillofacial surgery
- Bone graft models for mandible/maxilla regenerative procedures
- Dental and maxillofacial prosthesis

5 Indications for use

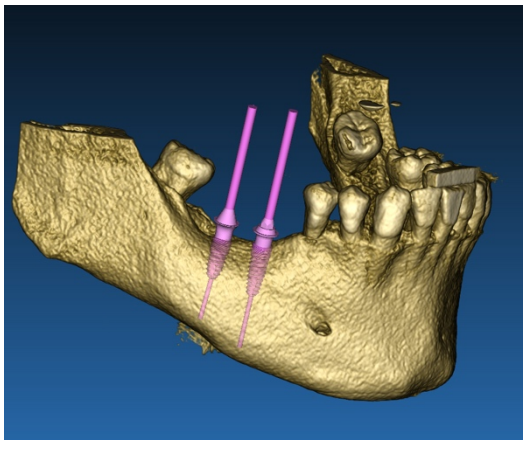
PC/MAC version
The RealGUIDE software is intended for the following uses:

1. *Support to the diagnosis for trained professionals*. The input DICOM files acquired by a CT/CBCT scanner are not modified in any way but they are showed to the doctor through the classical imaging and volume rendering techniques. It is a stand-alone product. No information of the patient is modified, all the parameters used for the image processing are read from the DICOM file itself. Neither automatic diagnosis is made, nor automatic disease detection is performed. This software is not connected to any medical instrumentation and it doesn't control any medical or energy supplying device. The user imports DICOM data coming from any CT/CBCT imaging device and the software enables him to view the Patient exam in different multi-planar 2D images and easily reconstruct the 3D volume for an immediate visualization of bone structures and surrounding tissues.



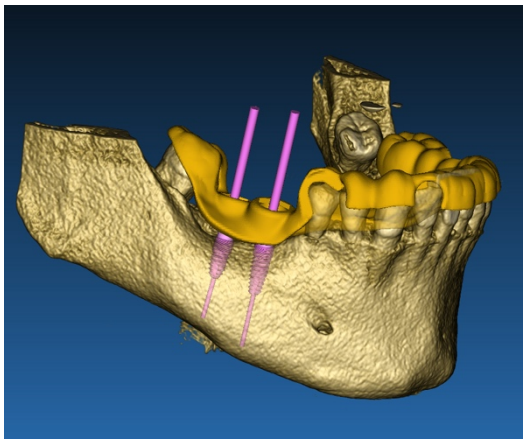
3D reconstruction from DICOM example

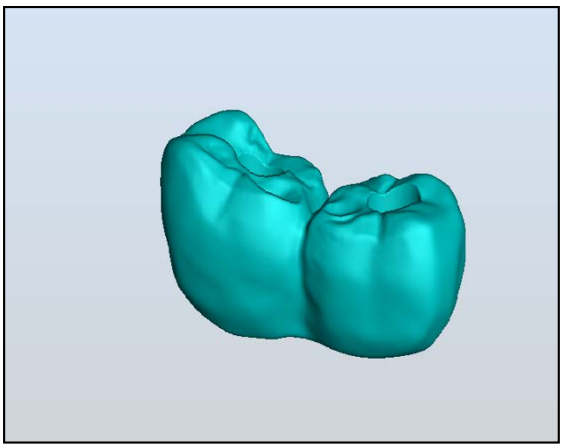
2. *Virtual oral and maxillofacial surgery planning*. Doctors can plan virtual implants and surgeries on 2D/3D reconstructions and export the projects in open or proprietary format for further processing. The user can choose different implant models (for example dental implants models) from a library provided by the Manufacturers and simulate the positioning in the Patient reconstructed volume (this operation is called "virtual plan")



Virtual implants plan

3. *Dental/maxillofacial surgical guides and prosthetic modelling*. The virtual plan is used to design a surgical guide that is used by the doctor to drive the surgery drills according to the planned implants direction and depth. This surgical guide can be manufactured by any 3D printer working from STL files. The user can also design the patient prosthesis (typically a denture) with the surface and volume free-form tools implemented in the software. The result is exported in STL format for 3D printing or CAD/CAM technologies.





Surgical guide designed to correctly drive the surgical drills and modelled teeth prosthesis

Mobile version

The RealGUIDE software APP is intended for the following uses:

1. *Projects visualization and editing*. The input PROJECT files, pre-processed with the RealGUIDE desktop version, are used by trained professionals to evaluate the implants projects, edit them and share them with other colleagues through the cloud, as well as for a more effective Patient treatment communication.

The RealGUIDE APP version is NOT INTENDED for managing a 3D diagnosis starting from DICOM images, due to the mobile devices screen resolution limitations. For this reason, the APP is not reading directly the DICOM files but only pre-processed project files, exported through the cloud by the RealGUIDE desktop version.

6 Comparison of technological characteristics with the predicate device

A comparison of the predicate device, reference devices, and RealGUIDE shows that many of the technological characteristics of the devices are similar. The differences between the predicate device and reference devices do not raise new questions of safety and effectiveness.

Feature name	RealGUIDE	3Shape Implant Studio 2015	Dentsply Simplant 2011	Straumann Codiagnostix	nSequence Maven PRO

510(k) number		K152078	K110300	K130724	K130242
DICOM 2D/3D reconstruction	Yes	Yes	Yes	Yes	Yes
Segmentation of anatomy and dentures	Yes	Yes	Yes	Yes	Yes
Import and matching STL files	Yes	Yes	Yes	Yes	Yes
Implant planning from library	Yes	Yes	Yes	Yes	Yes
Surgical guides design	Yes	Yes	Yes	Yes	No
Prosthesis design and connection with lab software	Yes	Yes	No	Yes	No
PC version	Yes	Yes	Yes	Yes	Yes
Mac version	Yes	No	No	No	Yes
Mobile version	Yes	Yes	No	Yes	No

Also the hardware requirements for the correct software use (reported….) are equivalent to the predicate and reference devices.

7 Performance data

The verification, validation and test of the RealGUIDE system have been conducted in accordance with the applicable 3DIEMME procedures and the RealGUIDE SVP documents. The test procedures and results are listed in the *RealGUIDE® Software System Validation Procedure (SVP) – Part 1-2* documents. Further details on the non-clinical tests and comparison between the RealGUIDE and the predicate device performance are reported in the *RealGUIDE® Software System Validation Procedure (SVP)* document.

The risk analysis for the device was conducted according to the EN ISO 14971:2012 (details reported in the *RealGUIDE® Software Hazard Analysis* document.

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

8 Clinical data

The software has been tested as a post-treatment information instrument to verify that the data shown by RealGUIDE were correspondent to the patient's anatomical features. Significant clinical studies have been performed by different medical professionals on many CT/CBCT images. The results of these studies are provided in a separate supplement to this submission. These clinical results show the effectiveness of the RealGUIDE software to improve the patient's surgical planning and the whole diagnostic approach.
Relevant scientific literature has been published to date on the effectiveness of medical imaging technology, applied to all the different medicine specialties. Several articles have been published by the leading doctors regarding the functions RealGUIDE is providing, and are listed in the *RealGUIDE® Software Description* document. Scientific literature about the use and testing of the applied algorithms in the medical field is reported in the *RealGUIDE® Software System Validation Procedure (SVP)* document.
Based on the clinical performance documented above, the RealGUIDE software has a safety and effectiveness profile that is similar to the predicate and reference devices.

9 Conclusion

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