



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Media Lab S.r.l.
% Mr. Massimo Ivani
CEO
Via Trieste 4
Follo, La Spezia 19020
ITALY

February 25, 2016

Re: K153091
Trade/Device Name: IMPLANT 3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 19, 2016
Received: February 23, 2016

Dear Mr. Ivani:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the typed name and title.

For

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

Enclosure

Indications for Use

510(k) Number (if known)

K153091

Device Name

IMPLANT 3D

Indications for Use (Describe)

Implant 3D is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CAT scanner.

It is also intended as pre-planning software for dental implant placement.

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

SUBMITTER/510(K) HOLDER:

Company Name: MEDIA LAB S.R.L.
Company Address: Via Trieste 4
19020 Follo - Italy
Company Phone: 039- 0187517775
Company Fax: 039- 0187511833
Company e-mail: massimo.ivani@mlsw.com
Contact person: Mr. Massimo Ivani
CEO
Date Summary Prepared: October 19, 2015

DEVICE IDENTIFICATION

Common Usual Name: Image processing system and software for evaluating dental implant placement
Trade/Proprietary Name: IMPLANT 3D
Classification: Class II
Product Code: LLZ
Classification Panel: 892 Radiology Devices
Regulation Number: 892.2050

LEGALLY MARKETED PREDICATE DEVICE

Predicate device	510 (k) Holder	510 (k) No.
SIMPLANT 2011	MATERIALISE DENTAL NV	K110300

DEVICE DESCRIPTION

Implant 3D is a software that allows to perform three-dimensional implant simulation directly on the PC. It enables to simulate the position of the implants in bi-dimensional and three-dimensional models. It also consent to identify the mandibular canal and to draw overviews and sections of the bone mode. Implant 3D enables to view the three-

dimensional bone model with the possibility to provide a qualitative indication of bone density.

Implant 3D generates the overview, the sections and the three-dimensional bone model by reading the axial images.

INDICATIONS FOR USE STATEMENT

Implant 3D is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CAT scanner. It is also intended as pre-planning software for dental implant placement.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

MEDIA LAB S.R.L. claims substantial equivalence of IMPLANT 3D to the predicate device based on the intended use, fundamental technology, and operation characteristics. A side-by-side comparison of IMPLANT 3D and the cited predicate device is included below.

ATTRIBUTE / CHARACTERISTICS	IMPLANT 3D (Submitted Device)	LEGALLY MARKETED PREDICATE DEVICES OF Materialised Dental NV
510(k) number	NA	K110300
Device Name	IMPLANT 3D	SIMPLANT 2011
CFR Section	892.2050	892.2050
Pro-code	LLZ	LLZ
Device Class	II	II
Classification panel	Radiology	Radiology
Intended / Indications For Use	Implant 3D is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CAT scanner. It is also intended as pre-planning software for dental implant.	SimPlant 2011 is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance scanner. It is also intended as pre-planning software for dental implant placement and surgical treatment.
Materials	Software – Magnetic Media	Software – Magnetic Media
Design	Software for use in pre-operative planning.	Software for use in pre-operative planning.
Functions	IMPLANT 3D provides a means for transferring patient images from a medical scanner to an output file. IMPLANT 3D is used to provide a means for advanced pre-operative planning of dental implant placements. IMPLANT 3D contains a library of dental implants	SimPlant 2011 provides a means for transferring patient images from a medical scanner to an output file. SimPlant 2011 is used to provide a means for advanced pre-operative planning of dental implant placements and orthognatic treatment. SimPlant 2011 contains a library of

	Surgical templates may be designed and fabricated based on the output of the pre-operative planning.	dental implants Surgical templates may be designed and fabricated based on the output of the pre-operative planning.
Operating System	Windows , MAC OS with Parallel Desktop	Windows
Hardware testing	N/A	N/A
Software testing	<ul style="list-style-type: none"> • Unit testing • Integration testing • IR testing • Smoke testing • Formal testing. • Acceptance testing • Alpha testing • Beta testing 	<ul style="list-style-type: none"> • Unit testing • Integration testing • IR testing • Smoke testing • Formal testing. • Acceptance testing • Alpha testing • Beta testing

PERFORMANCE DATA

MEDIA LAB S.R.L. has conducted laboratory testing and determined device functionality and conformance to design input requirements.

The device has been designed and validated in such a way that, when used under the conditions and for the purposes intended, it will not compromise the clinical condition or the safety of patients, or the safety and health of users or other people, provided that any risk which may be associated with its use constitute acceptable risks when weighed against the benefits to the patient and is compatible with a high level of protection of health and safety.

CONCLUSION

Based on the foregoing, IMPLANT 3D is substantially equivalent to the legally marketed, claimed predicate device for the purposes of this 510 (k) submission. Safety and effectiveness were reasonably assured, justifying 510 (k) clearance.