K081402

JUL 18 2008

SUBMITTER'S NAME AND ADDRESS:	MATERIALISE DENTAL N.V. Technologielaan 15 B-3001 Leuven, Belgium
ESTABLISHMENT REGISTRATION NO:	3006638827
CONTACT PERSON:	Carl Van Lierde, Materialise Dental N.V. Quality Manager +32 163 967 14 (tel) +32 163 966 22 (fax) carl.vanlierde@materialise.be
SUMMARY PREPARATION DATE:	April 21, 2008
TRADE NAME:	SimPlant Ortho; Vistadent 3D
COMMON NAME:	Image processing system and software for simulating /evaluating dental orthodontic treatment i.e. dental bite options
CLASSIFICATION NAME:	System, Image Processing (C.F.R. Section 892.2050, Product code: LLZ)
PREDICATE DEVICE	SimPlant System; SimPlant Dr. James (K053592)

FUNCTION

Simplant Ortho provides a method of **segmenting** CT images. This file allows the individual patient's CT image to be assessed in a three-dimensional way, to see the anatomical structures without patient contact or surgical insult. It includes features for **cephalometric analysis** of the patient and **orthodontic treatment simulation.** Additional information about the exact geometry of the tooth surfaces can be visualized together with the CT data and orthodontic procedures with TADs (temporary anchorage devices) can be simulated.
Osteotomies and distractions can be visualized to simulate the desired relation of both jaws and the result on the soft tissue profile of the patient can be visualized.
The output file is intended to be used in conjunction with diagnostic tools and expert clinical judgment.

INTENDED USE

Materialise Dental's **SimPlant Ortho; Vistadent 3D** software is indicated for use as a medical front-end software that can be used by medically trained people for the purpose of visualizing gray value images. It 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 used as a software system for simulating/evaluating orthodontic treatment i.e. dental bite options.

TESTING & VALIDATION

The software is thoroughly tested in accordance with a documented test plan. This test plan is derived from the specifications and ensures that all controls and features are functioning properly. The software is validated together with end-users.

TECHNOLOGICAL CHARACTERISITICS

SimPlant Ortho; Vistadent 3D is software for simulating/evaluating orthodontic treatment (i.e. dental bite options) programmed in C++ language and running on the Windows operating system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2008

Mr. Carl Van Lierde
Quality Manager
Materialise Dental NV
Technologielaan 15, 3001 Leuven
BELGIUM

Re: K081402
Trade/Device Name: SimPlant Ortho; Vistadent 3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 21, 2008
Received: May 19, 2008

Dear Mr. Lierde:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please ~~contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at~~ one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081402

Device Name: SimPlant Ortho; Vistadent 3D

Indications for Use:

Materialise Dental's **SimPlant Ortho; Vistadent 3D** software is indicated for use as a medical front-end software that can be used by medically trained people for the purpose of visualizing gray value images. It 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 used as a software system for simulating/evaluating orthodontic treatment i.e. dental bite options.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K081402