SEP 2 6 2011

510(k) Summary

K111641

Submitter information

Company name	Materialise N.V.
Establishment registration number	3003998208
Street Address	Technologielaan 15
City	Leuven
Postal code	3001
Country	Belgium
Phone number	+32 16 74 45 37
Fax number	+32 16 39 66 06
Principal contact name	Oliver Clemens
Contact title	Quality & Regulatory officer
Contact e-mail address	oliver.clemens@materialise.be
Additional contact name	Alexandra Razzhivina
Contact title	Regulatory officer
Contact e-mail address	alexandra.razzhivina@materialise.be
Additional contact name	Dieter Vandoren
Contact title	Continuous Improvement Manager CMF
Contact e-mail address	Dieter.vandoren@materialise.be

Submission date

The date of the Traditional 510(k) submission is June 10th, 2011

Submission information

Trade Name	SurgiCase, SurgiCase CMF, ProPlan CMF
Common Name	Image processing system and software for simulating/evaluating implant placement and surgical treatment options
Classification Name	System,Image processing, Radiological
Product code	LLZ (21 CFR 892.2050)

Predicate device

Trade or proprietary or model name	SurgiCase
510(k) number	K073449
Decision date	2008/04/16
Product code	LLZ
Manufacturer	Materialise N.V.

Device Information

Description of the device

This submission is a Traditional 510(k) for the Orthognathic wizard of SurgiCase software application.

SurgiCase is software for pre-operative simulation of orthognathic surgical treatment options, based on imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging (MRI) scanner.

Based on the software planning several options are available to transfer the result of the planning to surgery. Examples:

- The software planning can be used to select appropriate implants or implant sizes for use during surgery.
- Based on the planning, patient-specific surgical guides and implants can be designed.
- Patient-specific surgical splints[2] can be generated to transfer the planned dental occlusion to surgery.

Functioning of the device

The SurgiCase software platform is the basis of all clinical Materialise software designed for surgery planning. The platform allows basic functionality such as visualizing 3D objects, visualizing medical image data, generating 3D objects from medical image data and measuring.

On top of this platform, modules, also called wizards, can be added that each offer additional functionality such as planning a specific surgical routine. This platform is the main general wizard, while additional modules (wizards) are mainly based on the functionality of this general wizard; they assist the surgeon to plan specific surgery types step-by-step by providing each a different user interface, giving the surgeon the opportunity to fine tune parameters specific for that type of surgery. Current premarket notification is only for the Orthognathic wizard of the SurgiCase software. The rest of software wizards have been cleared under K073449 submission for the SurgiCase software.

Intended use

SurgiCase is software for pre-operative simulation of orthognathic surgical treatment options, based on imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging (MRI) scanner.

[2] The surgical splints are Class I, 510k exempt and therefore are not submitted for review in this 510k submission. References to the splints are provided as an example throughout this submission to give a complete overview on the whole process (from planning to surgery).

Summary of technological characteristics

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate device.

Performance data

Non-clinical testing

Software verification and validation testing will be completed by the end of August 2011. Verification and validation reports will be on file at Materialise from that point on and can be sent on request.

Clinical testing

Not applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Mr. Oliver Clemens
Quality and Regulatory Officer
Materialise NV
Technologielaan 15
3001 Leuven
BELGIUM

SEP 26 2011

Re: K111641
Trade/Device Name: SurgiCase Orthognathic software Wizard
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 1, 2011
Received: September 2, 2011

Dear Mr. Clemens:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: SurgiCase Orthognathic software wizard

Indications for Use:

SurgiCase is software for pre-operative simulation of orthognathic surgical treatment options, based on imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging (MRI) scanner.

Prescription Use _ X ____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __ _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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