K103136

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MAR 18 2011

510(k) Summary

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 39 62 80
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Contact name	Alexandra Razzhivina
Contact title	Regulatory affairs officer
Contact e-mail address	alexandra.razzhivina@materialise.be

Submission date

The date of the Traditional 510(k) submission is 21st October 2010.

Submission information

Trade Name	SurgiCase Guides
Common Name	Bone plate
Classification Name	Bone plate
Product code	JEY , MQN (21 CFR 872.4760)

Predicate devices

Trade or proprietary or model name	Zimmer Patient Specific Instruments System 2.0
510(k) number	K093533
Decision date	2010/02/17
Product code	MBH, JWH
Manufacturer	Materialise N.V.

Trade or proprietary or model name	Smith and Nephew Patient Matched Cutting Blocks
510(k) number	K082358
Decision date	2008/11/25
Product code	JWH, MBH
Manufacturer	Smith and Nephew, Inc.

Device Information

Description and functioning of the device

The SurgiCase Guides are patient specific devices or templates that are based on a pre-operative software planning and are designed to fit a specific patient. These templates are used to assist a surgeon in transferring this pre-operative plan to the surgery by guiding the marking of bone and/or guiding surgical instruments. A standardized design and manufacturing process with detailed procedures and work instructions allows manufacturing patient-specific templates that consistently perform in a safe and effective way during surgery.

The SurgiCase Guides are based on a software planning generated using the previously cleared SurgiCase software (K073449).

SurgiCase is software for pre-operative simulation and evaluation of implant placement and surgical treatment options, based on imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging (MRI) scanner. The SurgiCase software was previously reviewed under K073449 and is not submitted for review in this 510k submission. References to the software are included to give a complete overview on the guide design process.

Intended use

SurgiCase Guides are intended to be used as surgical tools to transfer a pre-operative plan to the surgery. The devices are intended to guide the marking of bone and/or guide surgical instruments in mandibular and maxillofacial surgical procedures.

SurgiCase Guides are intended for single use only.

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 tests

Non-clinical tests such as quantitative validation using bone models and cadaveric specimens, biocompatibility test, sterilization dimensional stability test and packaging and shipment test were performed to assess the safety and effectiveness of the device. Testing verified that the accuracy and performance of the system is adequate to perform as intended.

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. Alexandra Razzhivina
Regulatory Affairs Officer
Materialise NV
Technologielaan 15
Leuven, Belgium 3001

MAR 18 2011

Re: K103136
Trade/Device Name: SurgiCase Guides
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: March 10, 2011
Received: March 16, 2011

Dear Mr. Razzhivina:

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.

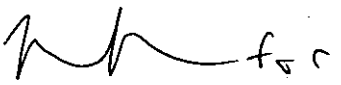
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K103136

Device Name: SurgiCase Guides

Indications for Use:

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SurgiCase Guides are intended for single use only.

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)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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