

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
Fax number	+32 16 39 66 06
Contact name	Alexandra Razzhivina
Contact title	Regulatory Officer
Contact e-mail address	alexandra.razzhivina@materialise.be

Submission date

The date of the Traditional 510(k) submission is March 27th, 2012.

Submission information

Trade Name	SurgiCase Guide
Common Name	Craniofacial Osteotomy Guide
Classification Name	Stereotaxic Instrument
Product code	HAW (21 CFR 882.4560)

Predicate devices

Trade or proprietary or model name	SurgiCase Guides
510(k) number	K103136
Decision date	2011/03/18
Product code	JEY, MQN
Manufacturer	Materialise N.V.

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. Guides are individually designed and manufactured for each patient using a design and manufacturing process with strict procedures and work instructions to guarantee templates that consistently perform in a safe and effective way.

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

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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 during craniofacial osteotomies.

The principal difference between the subject and predicate device is with respect to the anatomical region where the guides will be applied – craniofacial for the subject guides versus mandibular and maxillary for the predicate guides.

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, material and performance characteristics to the predicate device.

The proposed device has the same principles of operation as the predicate device: Each guide, made from polyamide, consists of a basic shape that fits the patient's anatomy and serves as an anatomical reference to position the guide on the surgical site. For each planned drill location, a functional element for drilling is added to the base shape and for each planned bone cut, a functional element for cutting is added.

Performance data

Non-clinical tests

Non-clinical tests included to assess the safety and effectiveness of the device:

- Quantitative validation using bone models and cadaveric specimens to validate the accuracy the guides obtain in transferring a surgical planning to the actual surgery during craniofacial osteotomies. Qualitative validation to evaluate the fit and stability of the guides.
The guides meet the predefined acceptance criteria.
- Biocompatibility testing: According to the results of biocompatibility testing on the finished device, the biocompatibility requirements have been met. Cytotoxicity testing was also performed on the finished device after sterilization. The finished product was determined to be non-cytotoxic.
- Sterility testing: A sterilization dimensional stability test was performed to verify the device does not deform more than the predefined production tolerance after two sterilization cycles. A sterility test demonstrates that the device can be successfully sterilized with the recommended sterilization parameters.
- A packaging and shipment test was performed to demonstrate the device can be safely shipped without

Conclusion: Testing verified that the accuracy and performance of the system is adequate to perform as intended.

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Clinical tests

No clinical testing was performed to support this submission.

Substantial equivalence to predicate devices

In conclusion, the SurgiCase Guides have similar intended use, principles of operation and performance characteristics compared to the predicate device. The only difference in intended use is the surgical region where the guides will be applied: cranial for the subject guides versus mandibular and maxillary for the predicate device.

Non-clinical testing data demonstrates that the accuracy and performance of the system is adequate to perform as intended during craniofacial osteotomies. The information presented supports substantial equivalence of these SurgiCase Guides to the predicate device for this new indication.



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

Materialise NV
c/o Mr. Oliver Clemens, Quality and Regulatory Officer
Technologielaan 15
3001 Leuven
Belgium

MAR 27 2012

Re: K111558

Trade/Device Name: Surgicase Guides
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: March 7, 2012
Received: March 9, 2012

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. 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" (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/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111558

Indications for Use

510(k) Number (if known): K111558

Device Name: SurgiCase Guides (for cranial application)

Indications for 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 during craniofacial osteotomies.

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)


(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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 X
Prescription Use
(Per 21 CFR 801.109)