K112389.

510(k) Summary

JUL 20 2012

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	regulatory.affairs@materialise.be

Submission date

The date of the Traditional 510(k) submission is 16th of August, 2011.

Submission information

Trade Name	SurgiCase Orthopaedics, SurgiCase Connect, SurgiCase Guides
Common Name	Image processing system and software for simulating/evaluating implant placement and surgical treatment options
Classification Name	Radiological image processing system
Product code	PBF

Predicate devices

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

Trade or proprietary or model name	SurgiCase Guide
510(k) number	K103136
Decision date	2011/04/18
Product code	JEY, MQN
Manufacturer	Materialise N.V.

Device Information

Description and functioning of the device

The SurgiCase Orthopaedics system is composed of two components: SurgiCase Connect (software) and SurgiCase Guides (hardware).

The SurgiCase Orthopaedics system is intended to be used as a surgical instrument to transfer a pre-surgical plan to the lower and upper extremity during orthopaedic surgical procedures.

SurgiCase Connect is a medical device for Materialise and a surgeon for pre-surgical simulation and evaluation of surgical treatment options. This includes transferring, visualizing, measuring, annotating and editing medical data.

The SurgiCase Guides are patient specific templates that are based on a pre-surgical software plan and are designed to fit a specific patient. All guides are individually designed and manufactured for each patient using a design and manufacturing process with strict procedures and work instructions to guarantee guides that consistently perform in a safe and effective way. In surgery these guides are used to assist a surgeon in guiding the marking of bone and/or guiding surgical instruments according to the pre-surgical plan.

Intended use

The SurgiCase Orthopaedics system is intended to be used as a surgical instrument to assist in pre-operative planning and/or in guiding the marking of bone and/or guide surgical instruments in non-acute, non-joint replacing osteotomies for upper extremity orthopedic surgical procedures.

The system is to be used for adult patients.

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 devices.

Performance data

Non-clinical tests

The SurgiCase Connect software has been validated for its intended use to determine substantial equivalence to the predicate devices.

SurgiCase Guides were validated through non-clinical studies using bone models and cadaver specimens. Biocompatibility test, sterility test, sterilization dimensional stability test, debris test and packaging and shipment test and cleaning validation test were performed to assess the safety and effectiveness of the SurgiCase Guides. Testing verified that the accuracy and performance of the device 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

Materialise N.V.
% Ms. Alexandra Razzhivina
Technologielaan 15
Leuven, Belgium 3001

JUL 30 2012

Re: K112389
Trade/Device Name: Surgicase Connect, Surgicase Guide
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: PBF
Dated: July 06, 2012
Received: July 09, 2012

Dear Ms. Razzhivina:

This letter corrects our substantially equivalent letter of July 20, 2012 for the product code and regulation number for your medical device. 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 (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 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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K112389

Device Name: The SurgiCase Orthopaedics system

Indications for Use:

The SurgiCase Orthopaedics system is intended to be used as a surgical instrument to assist in pre-operative planning and/or in guiding the marking of bone and/or guide surgical instruments in non-acute, non-joint replacing osteotomies for upper extremity orthopedic surgical procedures.

The system is to be used for adult patients.

SurgiCase Guides are intended for single use only.

(Division Sign-Off)
Division of Surgical, Orthopedic
and Restorative Devices

510(k) Number K112389

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