DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 18, 2017

Materialise N.V.
Oliver Clemens
Regulatory Officer
Technologielaan 15
Leuven, BE 3001
Belgium

Re: K163156
Trade/Device Name: Surgicase Orthopaedics, Surgicase Connect, Surgicase Guides
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: PBF
Dated: November 4, 2016
Received: November 10, 2016

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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 -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163156

Device Name
SurgiCase Orthopaedics system

Indications for Use *(Describe)*
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 adult patients; in upper extremity orthopedic surgical procedures and orthopedic surgical procedures around the knee.
• For pediatric patients 7 years of age and older; in orthopedic surgical procedures involving the radius and ulna.

SurgiCase Guides are intended for single use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitter information

Company name	Materialise N.V.
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Phone number	+32 16 39 62 80
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Contact name	Oliver Clemens
Contact title	Regulatory officer
Contact e-mail address	regulatory.affairs@materialise.be

Submission date

The date of the Traditional 510(k) submission is November 4th, 2016.

Submission information

Trade Name	**SurgiCase Orthopaedics** system, **SurgiCase Connect**, **SurgiCase Guides**
Common Name	Orthopaedic surgical planning and instruments guide
Classification Name	Orthopaedic surgical planning and instruments guide
Product code	PBF

Predicate devices

Trade or proprietary or model name	**SurgiCase Orthopaedics** system
510(k) number	K132290
Decision date	04/10/2014
Product code	PBF
Manufacturer	Materialise N.V.

Device Information

Description and functioning of the device

The **SurgiCase Orthopaedics** system is intended to be used as a surgical instrument to transfer a pre-surgical plan to surgeries involving osteotomies in upper extremity orthopedic surgical procedures and orthopedic surgical procedures around the knee.
For pediatric patients 7 years of age and older, it is intended to be used in osteotomies involving the radius and ulna.

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

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 designed and manufactured based on a pre-surgical software plan for a specific patient. In surgery these guides are used to assist a surgeon in guiding the marking of bone and/or guiding surgical instruments to cut and drill according to the pre-surgical plan.

All guides are individually designed and manufactured for each patient using a design and manufacturing process with strict procedures and work instructions. Part of this process is a scientific Stability Model which measures the sensitivity of a guide to movement during surgery. The use of this Stability Model provides a way to find the most stable position of the base plate on the individual patient's anatomy for accurate guiding of surgical instruments. The Stability Model is anatomy independent, thus it can be applied to any bony structure in upper and lower extremity surgical procedures.

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 adult patients; in upper extremity orthopedic surgical procedures and orthopedic surgical procedures around the knee.
- For pediatric patients 7 years of age and older; in orthopedic surgical procedures involving the radius and ulna.

SurgiCase Guides are intended for single use only.

Summary of technological characteristics

The proposed device has the same design, functionality, fundamental technology, materials, and software components as the predicate device (K13290). The only difference between the proposed device and the predicate device (K132290) is the intended patient population of the proposed device which has been expanded to the radius and ulna in pediatric patients 7 years of age and older. Since pediatric patients may not be fully grown, the guide might not adequately fit on the patient when too much time has passed between scan and surgery. Performance testing was conducted to address this concern.

Performance data

Non-clinical testing

In terms of biocompatibility, sterility, sterilization dimensional stability, cleaning, packaging and shipment, the SurgiCase Guides are identical to the predicate device. No new tests on these topics are needed.

The functional elements on the guides, i.e. drill sleeves, cutting slots, fixation holes, remain identical to the predicate device when used on a pediatric patient. The only part of the guide that requires extra testing is the base plate: the guide might not fit on the patient when too much time has passed between scan and surgery as the anatomy of the pediatric patient is likely to be growing. This changing anatomy is not a new risk compared to the predicate device, but the anatomical changes for pediatric patients are more profound. Several risk reduction measures are in place to account for a changing anatomy. One of the risk reduction measures is the useful life. The useful life period depends on the gender and the age of the patient, and the surgical area. The useful life is determined based on a literature study, covering both growth in length and growth in diameter of the bone, and fit tests. The goal of the fit tests was to determine the maximal allowed growth, which still ensures a good fit. The maximal allowed growth cannot be investigated by a sawbones or a cadaver lab, since those bones cannot grow. The only alternative is to simulate growth for pediatric bones coming from pediatric clinical cases. As such, a fit test is performed in which guides were placed on the grown, 3D-printed, pediatric bone models and evaluated.
Based on this maximal growth and the literature study the useful life is calculated as the period that can pass between scan date and surgery date without posing any risks with respect to the guide fit.

Due to the lack of literature on bone growth rates in pediatric patients, many extrapolations were made to the worst-case growth rate calculations and thereby the useful life calculations. Because of these extrapolations, multiple safety factors were incorporated into the useful life calculations, and in addition the shortest calculated useful life amongst all age/gender categories, i.e., 3 weeks, is to be used in all indicated pediatric patients. With a useful life of 3 weeks, indicated pediatric patients are not expected to have bone growth that would affect the performance of the proposed device. The proposed device is expected to perform substantially equivalent in indicated pediatric patients to the predicate device (K132290).

Like the predicate device, the additional use of a scientific Stability Model provides a way to find the most stable position of the base plate on the individual patient's anatomy for accurate guiding of surgical instruments. This Stability Model is anatomy independent and thus is applicable for pediatric bones as well.

Clinical testing

Retrospective analysis of US and OUS pediatric clinical cases helped to further support the safety and short-term efficacy of the proposed device.

Summary

All non clinical testing and the retrospective analysis of clinical cases indicate that the subject device is as safe, as effective, and performs as well as the predicate device.