



July 8, 2019

Materialise NV
Mieke Janssen
Regulatory Affairs Manager
Technologielaan 15
3001 Leuven
Belgium

Re: K190286

Trade/Device Name: Materialise Glenoid Positioning System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: June 4, 2019
Received: June 6, 2019

Dear Mieke Janssen:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CAPT Raquel Peat, PhD, MPH, USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K190286

Device Name

Materialise Glenoid Positioning System

Indications for Use (Describe)

Hardware

The Materialise Glenoid Positioning System is intended to be used as a surgical instrument to assist in the intraoperative positioning of glenoid components used with total and reverse shoulder arthroplasty by referencing anatomic landmarks of the shoulder that are identifiable on preoperative CT-imaging scans.

The Materialise Glenoid Positioning System can be used in conjunction with Stryker's following total and reverse shoulder implants systems and their respective compatible components: ReUnion RSA Reverse Shoulder System (K183039) and Reunion TSA Total Shoulder Arthroplasty System (K183039), with DJO's following total and reverse shoulder implant systems and their respective compatible components: Reverse® Shoulder Prosthesis (K051075, K111629, K092873), Turon® Shoulder System (K080402) and AltiVate™ Anatomic Shoulder System (K162024), with Lima's following total and reverse shoulder implant systems and their respective compatible components: SMR Shoulder System (K100858), SMR Reverse Shoulder System (K110598), SMR Modular Glenoid (K113254), SMR 3-Pegs Glenoid (K130642), SMR TT Metal Back Glenoid (K133349), SMR 40mm Glenosphere (K142139) and SMR Modular Glenoid (K143256), and with Depuy Synthes' following total and reverse shoulder implant systems and their respective compatible components: GLOBAL® APG+ Shoulder System (K052472), DELTA XTEND™ Reverse Shoulder System (K120174, K062250, K183077) and GLOBAL® STEPTECH® APG Shoulder System (K092122).

The Materialise Glenoid Positioning System Guide and Models are single use only.

Software

SurgiCase Shoulder Planner is intended to be used as a pre-surgical planner for simulation of surgical interventions for shoulder orthopedic surgery. The software is used to assist in the positioning of glenoid components. SurgiCase Shoulder Planner allows the surgeon to visualize, measure, reconstruct, annotate and edit pre-surgical plan data. The software leads to the generation of a surgery report along with a pre-surgical plan data file which can be used as input data to design the Materialise Glenoid Positioning Guide and Models.

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

The following section is included as required by the Safe Medical Devices Act (SMDA) of 1990 and 21CFR 807.92

Company name	Materialise N.V.
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Contact e-mail address	Regulatory.Affairs@materialise.be
Additional contact person	Ilke Vanhaelen
Contact title	Medical Device Development Engineer
Contact e-mail address	ilke.vanhaelen@materialise.be

Submission date

The date of the Traditional 510(k) submission is February 8, 2019.

Submission information

<i>Trade Name</i>	Materialise Glenoid Positioning System
<i>Common Name</i>	Patient specific instrumentation for shoulder arthroplasty + 3D planning software
<i>Classification Name</i>	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented
<i>Primary product code</i>	KWS (21 CFR 888.3660)

Predicate Device

The predicate device to which substantial equivalence is claimed:

<i>Trade or proprietary or model name</i>	Materialise Glenoid Positioning System Materialise Glenoid Positioning System Guide and Models SurgiCase Shoulder Planner
<i>510(k) number</i>	K172054
<i>Decision date</i>	November 3, 2017
<i>Classification product code</i>	KWS (21 CFR 888.3660)
<i>Manufacturer</i>	Materialise N.V.

Device Description

Materialise Glenoid Positioning System is a patient-specific medical device that is designed to be used to assist the surgeon in the placement of glenoid components.

This can be done by generating a pre-surgical plan or by generating a pre-surgical plan and manufacturing a patient-specific guide and models to transfer the plan to surgery. The device is a system composed of the following:

- a software component, branded as **SurgiCase Shoulder Planner**. This software is a planning tool used to generate a pre-surgical plan for a specific patient.
- a hardware component, branded as the **Materialise Glenoid Positioning System™ Guide and Models**, which is a patient specific guide and models that are based on a pre-surgical plan. This pre-surgical plan is generated using the software component. Patient-specific guide and models will be manufactured if the surgeon requests patient-specific guides to transfer the plan to surgery. The Materialise Glenoid Positioning System Guide is designed and manufactured to fit the anatomy of a specific patient. A bone model of the scapula is delivered with the Materialise Glenoid Positioning System Guide. A graft model can be delivered with the Materialise Glenoid Positioning System Guide.

The Materialise Glenoid Positioning Guide and Models must only be used within the intended use of the compatible components.

Indications for Use

Hardware

The **Materialise Glenoid Positioning System** is intended to be used as a surgical instrument to assist in the intraoperative positioning of glenoid components used with total and reverse shoulder arthroplasty by referencing anatomic landmarks of the shoulder that are identifiable on preoperative CT–imaging scans.

The **Materialise Glenoid Positioning System** can be used in conjunction with Stryker’s following total and reverse shoulder implants systems and their respective compatible components: ReUnion RSA Reverse Shoulder System (K183039) and Reunion TSA Total Shoulder Arthroplasty System (K183039), with DJO’s following total and reverse shoulder implant systems and their respective compatible components: Reverse®

Shoulder Prosthesis (K051075, K111629, K092873), Turon® Shoulder System (K080402) and AltiVate™ Anatomic Shoulder System (K162024), with Lima's following total and reverse shoulder implant systems and their respective compatible components: SMR Shoulder System (K100858), SMR Reverse Shoulder System (K110598), SMR Modular Glenoid (K113254), SMR 3-Pegs Glenoid (K130642), SMR TT Metal Back Glenoid (K133349), SMR 40mm Glenosphere (K142139) and SMR Modular Glenoid (K143256), and with Depuy Synthes' following total and reverse shoulder implant systems and their respective compatible components: GLOBAL® APG+ Shoulder System (K052472), DELTA XTEND™ Reverse Shoulder System (K120174, K062250, K183077) and GLOBAL® STEPTECH® APG Shoulder System (K092122).

The **Materialise Glenoid Positioning System Guide and Models** are single use only.

Software

SurgiCase Shoulder Planner is intended to be used as a pre-surgical planner for simulation of surgical interventions for shoulder orthopedic surgery. The software is used to assist in the positioning of glenoid components. SurgiCase Shoulder Planner allows the surgeon to visualize, measure, reconstruct, annotate and edit pre-surgical plan data. The software leads to the generation of a surgery report along with a pre-surgical plan data file which can be used as input data to design the Materialise Glenoid Positioning Guide and Models.

Functioning of the Device

The **Materialise Glenoid Positioning System** generates a pre-surgical plan based on medical imaging data using the *SurgiCase Shoulder Planner*. The software device then is used pre-operatively by a qualified surgeon to inspect, fine-tune and approve the pre-surgical plan. If requested by the surgeon, **Materialise Glenoid Positioning System Guide and models** are designed and manufactured based on the approved pre-surgical plan. **Materialise Glenoid Positioning System Guide and Models** are patient specific templates which transfer the pre-operatively determined pin positioning to the patient intra-operatively, assisting the surgeon in positioning glenoid components used with total and reverse shoulder arthroplasty procedures.

Technological Characteristics

A detailed comparison shows the subject device is substantially equivalent in intended use, design, functionality, operating principles, materials and performance characteristics to the predicate device, however extends the functionality of the SurgiCase Shoulder Planner to include showing of DICOM images, graft model visualization and a humerus visualization with subluxation index.

Performance Data

Previous testing for biocompatibility, sterility, cleaning, debris, dimensional stability and packaging are applicable to the subject device and demonstrate substantial equivalence with the predicate device. Testing verified that the accuracy and performance of the system is adequate to perform as intended. The stability of the device placement, surgical technique, intended use and functional elements of the subject device are the same as that of the predicate **Materialise Glenoid Positioning System** K172054 and previously cleared devices K170893, K153602 and K131559, and therefore previous cadaver testing on previously cleared devices K153602 and K131559 is considered applicable to the subject device.

Summary

The characteristics that determine the functionality and performance of the subject device are substantially equivalent to the predicate device cleared under K172054. The non-clinical testing indicates that the subject device

is as safe, as effective, and performs as well as the predicates. The **Materialise Glenoid Positioning System** will be manufactured in compliance with FDA (CFR 820 & Part 11) and ISO quality system (9000 and 13485) requirements.