Materialise NV
Veerle Vanderheyden
Regulatory Affairs Officer
Technologielaan 15
3001 Leuven
Belgium

March 20, 2020

Re: K193560
Trade/Device Name: Materialise Shoulder System, Materialise Shoulder Guide and Models, SurgiCase Shoulder Planner
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: QHE, KWS, PHX
Dated: December 20, 2019
Received: December 23, 2019

Dear Veerle Vanderheyden:

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,

Michael C. Owens
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193560

Device Name
Materialise Shoulder System

Indications for Use *(Describe)*

Hardware:

The Materialise Shoulder Guide and Models are 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 Shoulder Guide and Models are single use only.

The Materialise Shoulder Guide and Models can be used in conjunction with the following total and reverse shoulder implants systems and their respective compatible components:

- Depuy Synthes'
  - o GLOBAL® APG+ Shoulder System (K052472),
  - o DELTA XTEND™ Reverse Shoulder System (K120174, K062250, K183077)
  - o GLOBAL® STEPTECH® APG Shoulder System (K092122).
- DJO's
  - o Reverse® Shoulder Prosthesis (K051075, K111629, K092873),
  - o Turon® Shoulder System (K080402)
  - o AltiVate™ Anatomic Shoulder System (K162024)
- Integra's
  - o Titan™ Total Shoulder System (K100448, K112438, K142413, K152047)
  - o Titan™ Reverse Shoulder System (K130050, K161189, K173717, K181999)
- Lima's
  - o SMR™ Shoulder System (K100858),
  - o SMR™ Reverse Shoulder System (K110598),
  - o SMR™ Modular Glenoid (K113254) (K143256),
  - o SMR™ 3-Pegs Glenoid (K130642),
  - o SMR™ TT Metal Back Glenoid (K133349),
  - o SMR™ 40mm Glenosphere (K142139).
- Stryker's
  - o ReUnion RSA Reverse Shoulder System (K183039)
  - o Reunion TSA Total Shoulder Arthroplasty System (K183039).

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 shoulder 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 Shoulder 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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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Additional contact person	Sanne Willekens
Contact title	Technical product manager
Contact e-mail address	Sanne.willekens@materialise.be

Submission date

The date of the Traditional 510(k) submission is December 20, 2019.

Submission information

Trade Name	Materialise Shoulder System Materialise Shoulder Guide and Models SurgiCase Shoulder Planner
Common Name	Patient specific instrumentation for shoulder arthroplasty + 3D planning software
Classification Name	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Primary product code	QHE (21 CFR 888.3660); Shoulder Arthroplasty Implantation System
Additional product codes	KWS (21 CFR 888.3660); Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented; PHX (21 CFR 888.3660); Shoulder Prosthesis, Reverse Configuration

Predicate Device

The predicate device to which substantial equivalence is claimed:

Trade or proprietary or model name	Materialise Glenoid Positioning System Materialise Glenoid Positioning System Guide and Models SurgiCase Shoulder Planner
510(k) number	K190286
Decision date	July 8, 2019
Classification product code	KWS (21 CFR 888.3660)
Manufacturer	Materialise N.V.

Reference Device

Trade or proprietary or model name	BLUEPRINT™ Patient Specific Instrumentation
510(k) number	K162800
Decision date	February 22, 2017
Classification product code	KWS (21 CFR 888.3660)
Manufacturer	Tornier SAS

Device Description

Materialise Shoulder System is a patient-specific medical device that is designed to be used to assist the surgeon in the placement of shoulder components during total anatomic and reverse shoulder replacement surgery. This can be done by generating a pre-surgical shoulder plan and, if requested by the surgeon, by manufacturing a patient-specific glenoid guide and models to transfer the glenoid 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.

- **Materialise Shoulder Guide and Models,** which are 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 glenoid guide and models will be manufactured if the surgeon requests patient-specific guides to transfer the glenoid plan to surgery. The Materialise Shoulder Guide is designed and manufactured to fit the anatomy of a specific patient. A bone model of the scapula is delivered with the Materialise Shoulder Guide. A graft model can be delivered with the Materialise Shoulder Guide. The graft model visualizes the graft-space between implant and bone, based on the pre-operative planning of the surgeon. The graft serves as a visual reference for the surgeon in the OR.

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

Intended Use

Hardware

The **Materialise Shoulder Guide and Models** are 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 Shoulder Guide and Models** are single use only.

The **Materialise Shoulder Guide and Models** can be used in conjunction with the following total and reverse shoulder implants systems and their respective compatible components:

- Depuy Synthes'
  - GLOBAL® APG+ Shoulder System (K052472),
  - DELTA XTEND™ Reverse Shoulder System (K120174, K062250, K183077)
  - GLOBAL® STEPTECH® APG Shoulder System (K092122).
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  - Reverse® Shoulder Prosthesis (K051075, K111629, K092873),
  - Turon® Shoulder System (K080402)
  - AltiVate™ Anatomic Shoulder System (K162024)
- Integra's
  - Titan™ Total Shoulder System (K100448, K112438, K142413, K152047)
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  - SMR™ Modular Glenoid (K113254) (K143256),
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  - SMR™ TT Metal Back Glenoid (K133349),
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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 shoulder 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 Shoulder Guide and Models.

Functioning of the Device

The Materialise Shoulder System generates a pre-surgical plan based on medical imaging data using the SurgiCase Shoulder Planner. The SurgiCase Shoulder Planner allows a qualified surgeon to visualize, measure, reconstruct, annotate, edit and approve pre-surgical plan data, which leads to the generation of a case planning report. The SurgiCase Shoulder Planner (SCSP) allows for the creation of a glenoid and/or humeral pre-operative plan. If requested by the surgeon, Materialise Shoulder Guide and Models are designed and manufactured based on the approved glenoid pre-surgical plan. Materialise Shoulder 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. The Materialise Shoulder Guide and Models are available for glenoid components only.

Technological Characteristics

The Materialise Shoulder System has an equivalent intended use and the same fundamental scientific technology as the predicate and reference devices. The subject device's software is intended for positioning shoulder components, i.e. glenoid components (same as the predicate device) and humeral components. The subject device's hardware is intended for positioning shoulder glenoid components only (same as the predicate device).

Software

The subject software device employs similar fundamental technologies as the predicate software device. Technological similarities include:

- Device functionality: The planning functionality, visualization options and planning features are exactly the same for the glenoid planning of the subject device as for the predicate device
- Software technology: The subject device has the same code base as the predicate device and uses exactly the same methods for design and verification and validation as the predicate device.

Following technological differences exist between the subject device software and the predicate device software:

- The subject device software includes humeral planning, range of motion assessment, defect quantification and bone removal tool. However, the positioning options and visualization options available for humeral planning are technologically the same as for glenoid planning in the predicate device, only applied to a humeral component instead of a glenoid component. The humeral planning feature, range of motion functionality and bone removal tool are present in the reference device: BLUEPRINT™ Patient Specific Instrumentation (K162800).

The subject software technology differences have been demonstrated to not affect safety or effectiveness or raise new issues of safety or effectiveness compared to the predicate device.

Hardware

The subject hardware device is substantially equivalent in intended use, design, functionality, operating principles, materials and performance characteristics to the predicate device.

Performance Data (non-clinical)

Hardware:

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 K190286 and previously cleared devices K172054, K170893, K153602 and K131559, and therefore previous simulated surgeries using rapid prototyped bone models and previous cadaver testing on previously cleared devices K153602 and K131559 are considered applicable to the subject device.

Software:

Software verification and validation were performed and documentation was provided following the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." This includes verification against defined requirements, and validation against user needs.

Summary

The non-clinical performance testing indicates that the subject device is as safe, as effective, and performs as well as the predicate device. Therefore it can be concluded that the Materialise Shoulder System is substantial equivalent to the predicate device. The **Materialise Shoulder System** will be manufactured in compliance with FDA (CFR 820 & Part 11) and ISO quality system (13485) requirements.