



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

Materialise NV  
Mr. Oliver Clemens  
Regulatory Officer  
Technologielaan 15,  
Leuven 3001  
BELGIUM

April 26, 2016

Re: K153602

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: March 22, 2016  
Received: March 28, 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 Parts 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" (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 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

## Indications for Use

510(k) Number (if known)

K153602

Device Name

Materialise Glenoid Positioning System

Indications for Use (Describe)

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 ReUnion RSA Reverse Shoulder System (K130895) and its respective components, with DJO's Encore Shoulder System (K051075), Turon™ to RSP Conversion Shell (K111629), Turon™ Shoulder System (K080402) and Reverse® Shoulder prosthesis (K092873) and their respective components, and Lima's 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 their respective components.

The Materialise Glenoid Positioning System guide is 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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Materialise Glenoid Positioning System  
510(k) Premarket Notification

**510(k) Summary****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.
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
Principal Contact person	Oliver Clemens
Contact title	Regulatory Officer
Contact e-mail address	<a href="mailto:Regulatory.Affairs@materialise.be">Regulatory.Affairs@materialise.be</a>
Additional contact person	Filip Jonkergouw
Contact title	Product Manager
Contact e-mail address	<a href="mailto:Filip.Jonkergouw@materialise.be">Filip.Jonkergouw@materialise.be</a>

**Submission date**

The date of the Traditional 510(k) submission is December 15, 2015.

**Submission information**

<i>Trade Name</i>	Materialise Glenoid Positioning System
<i>Common Name</i>	Patient specific instrumentation for shoulder arthroplasty
<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:

Materialise Glenoid Positioning System  
510(k) Premarket Notification

**510(k) Summary**

<i>Trade or proprietary or model name</i>	Match Point System™, Match Point System™ guide, SurgiCase Connect
<i>510(k) number</i>	K131559
<i>Decision date</i>	September 27 <sup>th</sup> , 2013
<i>Classification product code</i>	KWS (21 CFR 888.3660)
<i>Manufacturer</i>	Materialise N.V.

**Device Description**

The **Materialise Glenoid Positioning System™** consists of a software component, SurgiCase Planner and a hardware component, Materialise Glenoid Positioning System™ guide, and is designed to assist the surgeon in the placement of glenoid components.

Materialise Glenoid Positioning Guides are patient-specific medical devices that are designed to be used to assist the surgeon in the placement of glenoid components.

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

**Intended Use**

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 ReUnion RSA Reverse Shoulder System (K130895) and its respective components, with DJO's Encore Shoulder System (K051075), Turon™ to RSP Conversion Shell (K111629), Turon™ Shoulder System (K080402) and Reverse® Shoulder prosthesis (K092873) and their respective components, and Lima's 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 their respective components.

The **Materialise Glenoid Positioning System guide** is single use only.

**Functioning of the Device**

The **Materialise Glenoid Positioning System** generates a pre-surgical plan based on medical imaging data using the *SurgiCase Planner*. The software device then is used pre-operatively by a qualified surgeon to inspect, fine-tune and approve the pre-surgical plan. Next, **Materialise Glenoid Positioning System guides** are designed and manufactured

Materialise Glenoid Positioning System  
510(k) Premarket Notification

### 510(k) Summary

based on the approved pre-surgical plan. **Materialise Glenoid Positioning System guides** 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 offers a web-based software application rather than a desktop application, extends the compatible implant families to Stryker implants cleared under K130895 and Lima implants cleared under K100858, K110598, K113254, K130642, K133349, K142139 and K143256 and includes an additional drill cylinder on the guide when used with K111629 and K080402, and expands the borders of use by replacing the anatomy based contraindication in K131559 with a contraindication based on a software restriction. The SurgiCase Shoulder Planner may restrict use for the Materialise Glenoid Positioning System when placement of the pilot wire (drill bit) is not optimal for implant placement. To ensure safety and effectiveness of the Materialise Glenoid Positioning System guides, the SurgiCase Shoulder Planner restricts the placement of the pilot wire (drill bit) within the intersection of two cones – a 45° cone from the neutral axis and a 60° cone from the normal of the glenoid face.

#### **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. **Materialise Glenoid Positioning System** was validated through non-clinical tests using rapid prototyped bone models to verify the system is adequate to perform as intended and to determine substantial equivalence. Cadaver testing validated the use of the subject device for use in total and reverse shoulder arthroplasty and demonstrated equivalent product performance as the existing predicate device (K131559).

#### **Summary**

The characteristics that determine the functionality and performance of the subject device are substantially equivalent to the predicate device cleared under K131559. 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.