June 9, 2026

Materialise NV
Giulia Girola
Regulatory Affairs Specialist
Technologielaan 15
Leuven, 3001
Belgium

Re: K260802
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: March 11, 2026
Received: March 11, 2026

Dear Giulia Girola:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FARZANA SHARMIN -S

Farzana Sharmin, Ph.D.
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260802

Device Name
Materialise Shoulder System™, Materialise Shoulder Guide and Models, SurgiCase Shoulder Planner

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'
• GLOBAL® APG+ Shoulder System (K052472)
• DELTA XTEND™ Reverse Shoulder System (K120174, K062250, K183077, K203694)
• GLOBAL® STEPTECH® APG Shoulder System (K092122)
• INHANCE™ Anatomic Shoulder System (K202716)[1]
• INHANCE™ Reverse Shoulder System (K212737)
• INHANCE™ Hybrid Anatomic Glenoid Implant (K212933)
• INHANCE™ Reverse Glenoid Peripheral Posts (K221467)
• INHANCE Convertible Glenoid (K230831)
- Enovis'2 (DJO)
• Reverse® Shoulder Prosthesis (K051075, K092873, K112069)
• Turon® Shoulder System (K080402, K123982)
• AltiVate™ Anatomic Shoulder System (K162024)
• AltiVate™ Anatomic Augmented Glenoid (K213387, K222592)
• AltiVate™ Reverse Glenoid (K233481)
- Smith+Nephew's3
• Titan™ Total Shoulder System (K100448, K112438, K142413, K152047)
• Titan™ Reverse Shoulder System (K130050, K161189, K173717, K181999)
• AETOS Total Shoulder System (K220847, K230572)
• AETOS Reverse Shoulder System (K220847, K230572)
- Lima's
• SMR™ Shoulder System (K100858)
• SMR™ Reverse Shoulder System (K110598)
• SMR™ Modular Glenoid (K113254) (K143256)
• SMR™ 3-Pegs Glenoid (K130642)
• SMR™ TT Metal Back Glenoid (K133349)
• SMR™ 40mm Glenosphere (K142139)
• SMR™ TT Augmented 360 Baseplate (K220792)
• SMR™ TT Hybrid Glenoid (K220792)
• PRIMA TT Glenoid (K222427, K252352)

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.

1 The implant system was originally cleared under K202716 as the Ignite Anatomic Shoulder System and was rebranded by DePuy Synthes as INHANCE™ Anatomic Shoulder System.
2 DJO company name changed to Enovis. The shoulder products of Enovis were originally cleared under the company name of DJO (Encore Medical).
3 The Integra shoulder portfolio was acquired by Smith+Nephew in 2020. The shoulder products of the Titan™ Shoulder System were transferred from Integra to Smith+Nephew.

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 - K260802

The following section is included as required by the Safe Medical Devices Act (SMDA) of 1990 and 21CFR 807.92.18

Company name	Materialise N.V.
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Primary contact person	Giulia Girola
Contact title	Regulatory Affairs Specialist
Contact e-mail address	Regulatory.Affairs@materialise.be
Additional contact person	Jenny Jones
Contact title	Global Quality Regulatory Manager
Contact e-mail address	Regulatory.Affairs@materialise.be

Submission date

The date of the Traditional 510(k) submission is March 11th 2026.

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)
Additional product codes	KWS (21 CFR 888.3660) PHX (21 CFR 888.3660)

Predicate Device

The predicate device to which substantial equivalence is claimed:

Trade or proprietary or model name	Materialise Shoulder System™ Materialise Shoulder Guide and Models SurgiCase Shoulder Planner

510(k) number	K242813
Decision date	October 18, 2024
Classification product code	QHE (21 CFR 888.3660) KWS (21 CFR 888.3660) PHX (21 CFR 888.3660)
Manufacturer	Materialise N.V.

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.

Indications for 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, K203694)
  - GLOBAL® STEPTECH® APG Shoulder System (K092122)
  - INHANCE™ Anatomic Shoulder System (K202716)[1]
  - INHANCE™ Reverse Shoulder System (K212737)

- INHANCE™ Hybrid Anatomic Glenoid Implant (K212933)
- INHANCE™ Reverse Glenoid Peripheral Posts (K221467)
- INHANCE Convertible Glenoid (K230831)

- **Enovis'**[2] (**DJO**)
    - Reverse® Shoulder Prosthesis (K051075, K092873, K112069)
    - Turon® Shoulder System (K080402, K123982)
    - AltiVate™ Anatomic Shoulder System (K162024)
    - AltiVate™ Anatomic Augmented Glenoid (K213387, K222592)
    - AltiVate™ Reverse Glenoid (K233481)

- **Smith+Nephew's**[3]
    - Titan™ Total Shoulder System (K100448, K112438, K142413, K152047)
    - Titan™ Reverse Shoulder System (K130050, K161189, K173717, K181999)
    - AETOS Total Shoulder System (K220847, K230572)
    - AETOS Reverse Shoulder System (K220847, K230572)

- **Lima's**
    - SMR™ Shoulder System (K100858)
    - SMR™ Reverse Shoulder System (K110598)
    - SMR™ Modular Glenoid (K113254) (K143256)
    - SMR™ 3-Pegs Glenoid (K130642)
    - SMR™ TT Metal Back Glenoid (K133349)
    - SMR™ 40mm Glenosphere (K142139)
    - SMR™ TT Augmented 360 Baseplate (K220792)
    - SMR™ TT Hybrid Glenoid (K220792)
    - PRIMA TT Glenoid (K222427, K252352)

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.

[1]The implant system was originally cleared under K202716 as the Ignite Anatomic Shoulder System and was rebranded by DePuy Synthes as INHANCE™ Anatomic Shoulder System.
[2]DJO company name changed to Enovis. The shoulder products of Enovis were originally cleared under the company name of DJO (Encore Medical).

[3] The Integra shoulder portfolio was acquired by Smith+Nephew in 2020. The shoulder products of the Titan™ Shoulder System were transferred from Integra to Smith+Nephew.

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 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 device. The subject device's software is intended for positioning shoulder components, i.e. glenoid components and humeral components (same as the predicate device). 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 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 the same methods for design and verification and validation as the predicate device.

Minor differences exist between software component of the subject device and the predicate device software.

The subject software technology differences have been demonstrated that they do not affect the safety or effectiveness, or that they do not raise any new issues regarding to the safety and 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 compared with the predicate device.

The main differences between the subject hardware device and the predicate device are the following additional features:

- Addition of an alternative shoulder guide and model configuration (glenoid rim fit).
- Inclusion of anterior hook option to the standard shoulder guide configuration.
- Inclusion of use in presence of pre-existing metal in scapula or surrounding tissues.

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.

Previous testing for biocompatibility, sterility, cleaning and packaging were performed on a worst-case design including worst case features that cover the whole range of design variations of the subject device. Since the design features of the subject device are covered in the worst-case design used for testing, these tests are still valid. Previous testing for debris is still valid because the drill sleeve, the critical element for debris generation, remains unchanged from the predicate device.
Previous testing for dimensional stability remains applicable because the subject device does not present features that create a new worst case scenario for dimensional stability compared to the features tested for the predicate device. Additional testing for packaging has been performed given the new packaging configuration.

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 device of Materialise Shoulder System™ K241143 and previously cleared devices K233408, K231112, K230315, K220452, K212569, K193560, K190286, 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.

Conclusion

The non-clinical performance testing indicates that the subject device is as safe and effective as the predicate device. Therefore, it can be concluded that the Materialise Shoulder System™ is substantially equivalent to the predicate device.