January 6, 2026

Materialise N.V.
Jenny Jones
Global Quality Regulatory Manager
Technologielaan 15
Leuven, 3001
Belgium

Re: K253793
Trade/Device Name: Materialise TKA Guide System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH, OIY, OOG, MBH
Dated: November 27, 2025
Received: November 28, 2025

Dear Jenny Jones:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

LIXIN LIU -S

Lixin Liu, 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253793

Please provide the device trade name(s).

Materialise TKA Guide System

Please provide your Indications for Use below.

Materialise TKA Guide System consists of hardware (Materialise TKA Guides and Models) and software (SurgiCase Knee Planner) components.

Hardware

• Pin Placement Guides
The Materialise TKA Guides are intended to be used as a surgical instrument to assist in the intra-operative positioning of Total Knee Replacement components and in guiding the marking of bone before cutting.

The Materialise TKA Guides must be used in conjunction with the Zimmer NexGen® CR-Flex fixed bearing, Zimmer NexGen® CR fixed bearing, Zimmer NexGen® LPS-Flex fixed bearing, Zimmer NexGen® LPS fixed bearing, Zimmer Gender Solutions® Natural-Knee® fixed bearing, Zimmer Persona® CR fixed bearing, Zimmer Persona® PS fixed bearing, Zimmer Persona® OsseoTi® Keel Tibia, Zimmer Persona® Cemented Keel Tibia, Zimmer Persona® PPS® Femur, Vanguard® Complete Knee System, Lima Physica PS System Knee System, Lima Physica CR Knee System, Lima Physica KR Knee System, Omni Apex CR, Omni Apex PS, Ortho Development BKS CR, Ortho Development BKS PS, Ortho Development BKS TriMax CR and Ortho Development BKS TriMax PS prostheses families only.

The Materialise TKA Guides are intended for single use only.

• Cut-Through Guides
The Materialise TKA Guides are intended to be used as a surgical instrument to assist in the intra-operative positioning of Total Knee Replacement components and in guiding the marking of bone before cutting and cutting of the bone.

The Materialise TKA Guides must be used in conjunction with the Vanguard® Complete Knee System, prostheses families only.

The Materialise TKA Guides are intended for single use only.

• Models
The Materialise TKA Models are intended to be used as a surgical instrument to assist in the intra-operative positioning of Total Knee Replacement components.

The Materialise TKA Models must be used in conjunction with Zimmer NexGen® CR-Flex fixed bearing, Zimmer NexGen® CR fixed bearing, Zimmer NexGen® LPS-Flex fixed bearing, Zimmer NexGen® LPS fixed bearing, Zimmer Gender Solutions® Natural-Knee® fixed bearing, Zimmer Persona® CR fixed bearing, Zimmer Persona® PS fixed bearing, Zimmer Persona® OsseoTi® Keel Tibia, Zimmer Persona® Cemented Keel Tibia, Zimmer Persona® PPS® Femur, Vanguard® Complete Knee System, Lima Physica PS System Knee System, Lima Physica CR Knee System, Lima Physica KR Knee System, Omni Apex CR,

Omni Apex PS, Ortho Development BKS CR, Ortho Development BKS PS, Ortho Development BKS TriMax CR and Ortho Development BKS TriMax PS prostheses families only.

The Materialise TKA Models are intended for single use only.

Software
The SurgiCase Knee Planner is intended to be used as a pre-surgical planner for knee orthopedic surgery. The software is used to pre-operatively plan the positioning of knee components. The SurgiCase Knee 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 is used as input data to design the Materialise TKA Guides and Models.

510(k) Summary

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.
Establishment registration number	3003998208
Street Address	Technologielaan 15
City	Leuven
Postal code	3001
Country	Belgium
Phone number	+32 16 39 66 11
Fax number	+32 16 39 66 06
Primary contact person	Gulia 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	Jenny.Jones@materialise.com

Submission date

The date of the Special 510(k) submission is November 27th, 2025.

Submission Information

Trade Name	*Materialise TKA Guide System*
Common Name	Patient specific instrumentation and 3D planning software for knee replacement
Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Primary product code	JWH (21 CFR 888.3560)
Additional product codes	OIY (21 CFR 888.3560) OOG (21 CFR 888.3560) MBH (21 CFR 888.3565)

Predicate Device

The predicate device to which substantial equivalence is claimed:

Primary predicate device:

Trade or proprietary or model name	Materialise TKA Guide System
510(k) number	K251554
Decision date	July 14, 2025
Classification product code	JWH (21 CFR 888.3560) OIY(21 CFR 888.3560) OOG (21 CFR 888.3560) MBH (21 CFR 888.3565)
Manufacturer	Materialise N.V.

Reference device:

Trade or proprietary or model name	Materialise PKA Guide System
510(k) number	K202207
Decision date	October 2, 2020
Classification product code	HSX (21CFR888.3520) OOG (21 CFR 888.3560)
Manufacturer	Materialise N.V.

Device Description

The Materialise TKA Guide System is a medical device designed to be used to implant total knee prosthesis components during a total knee arthroplasty surgical procedure. This can be done by generating a pre-surgical knee plan and by manufacturing a patient-specific knee guide and models to transfer the knee plan to surgery.

The subject device is a system that consists of the following two functional components:

- A software component branded as **SurgiCase Knee Planner**. This software is a planning tool used to generate a personalized pre-surgical TKA plan according to either a mechanical or a restricted kinematic alignment philosophy based on patient anatomy. This initial plan can then be further edited by the surgeon.

- Hardware components branded as **Materialise TKA Guides and Models**: which are patient-specific guides and models that are based on a pre-surgical plan. This pre-surgical plan is generated using the software component. Materialise TKA Guides and Models is an instrument set containing a femur and/or tibia guide(s) and bone models (optional). Both femoral and tibial guides are designed and manufactured to fit the anatomy of a specific patient. If the surgeon requests it, a bone model of the femur and/or tibia are delivered with the Materialise TKA Guides. The Materialise TKA Guides and Models assist in the intra-operative positioning of total knee replacement components. The guides assist in guiding the marking of bone before cutting and cutting of the bone. The models serve as a visual reference for the surgeon in the operating room. The Materialise TKA Guides and Models must only be used within the intended use of the compatible components (510(k) cleared, legally marketed prosthesis).

Indications for Use

Materialise TKA Guide System consists of hardware (Materialise TKA Guides and Models) and software (SurgiCase Knee Planner) components.

Hardware

- Pin Placement Guides

The *Materialise TKA Guides* are intended to be used as a surgical instrument to assist in the intra-operative positioning of Total Knee Replacement components and in guiding the marking of bone before cutting.

The *Materialise TKA Guides* must be used in conjunction with the Zimmer NexGen® CR-Flex fixed bearing, Zimmer NexGen® CR fixed bearing, Zimmer NexGen® LPS-Flex fixed bearing, Zimmer NexGen® LPS fixed bearing, Zimmer Gender Solutions® Natural-Knee® fixed bearing, Zimmer Persona® CR fixed bearing, Zimmer Persona® PS fixed bearing, Zimmer Persona® OsseoTi® Keel Tibia, Zimmer Persona® Cemented Keel Tibia, Zimmer Persona® PPS® Femur, Vanguard® Complete Knee System, Lima Physica PS System Knee System, Lima Physica CR Knee System, Lima Physica KR Knee System, Omni Apex CR, Omni Apex PS, Ortho Development BKS CR, Ortho Development BKS PS, Ortho Development BKS TriMax CR and Ortho Development BKS TriMax PS prostheses families only.

The *Materialise TKA Guides* are intended for single use only.

- Cut-Through Guides

The *Materialise TKA Guides* are intended to be used as a surgical instrument to assist in the intra-operative positioning of Total Knee Replacement components and in guiding the marking of bone before cutting and cutting of the bone.

The *Materialise TKA Guides* must be used in conjunction with the Vanguard® Complete Knee System, prostheses families only.

The *Materialise TKA Guides* are intended for single use only.

- Models

The *Materialise TKA Models* are intended to be used as a surgical instrument to assist in the intra-operative positioning of Total Knee Replacement components.

The Materialise TKA Models must be used in conjunction with Zimmer NexGen® CR-Flex fixed bearing, Zimmer NexGen® CR fixed bearing, Zimmer NexGen® LPS-Flex fixed bearing, Zimmer NexGen® LPS fixed bearing, Zimmer Gender Solutions® Natural-Knee® fixed bearing, Zimmer Persona® CR fixed bearing, Zimmer Persona® PS fixed bearing, Zimmer Persona® OsseoTi® Keel Tibia, Zimmer Persona® Cemented Keel Tibia, Zimmer Persona® PPS® Femur, Vanguard® Complete Knee System, Lima Physica PS System Knee System, Lima Physica CR Knee System, Lima Physica KR Knee System, Omni Apex CR, Omni Apex PS , Ortho Development BKS CR, Ortho Development BKS PS, Ortho Development BKS TriMax CR and Ortho Development BKS TriMax PS prostheses families only.

The *Materialise TKA Models* are intended for single use only.

Software

The SurgiCase Knee Planner is intended to be used as a pre-surgical planner for knee orthopedic surgery. The software is used to pre-operatively plan the positioning of knee components. The SurgiCase Knee 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 is used as input data to design the Materialise TKA Guides and Models.

Functioning of the Device

The Materialise TKA Guide System generates a pre-surgical plan based on MRI or CT images using the SurgiCase Knee Planner. The SurgiCase Knee Planner then is used pre-operatively by a qualified surgeon to inspect, fine-tune and approve the pre-surgical plan. Next, Materialise TKA Guides and Models (models are optional) are designed and manufactured based on the approved pre-surgical plan. Materialise TKA Guides are patient-specific templates which transfer the pre-operatively determined positioning of the chosen total knee replacement components to the patient intra-operatively, assisting the surgeon in positioning and aligning the actual total knee replacement components by guiding the marking of bone before cutting and to guide cutting of the bone. The patient-specific models serve as a visual reference for the surgeon in the operating room.

Technological Characteristics

The Materialise TKA Guide System has an equivalent intended use and the same fundamental scientific technology as the predicate device. The subject device's software is intended for simulation and planning of pre-operational intervention, and for positioning knee components, i.e., tibia and femur components (same as the predicate device and reference device). The subject device's hardware is intended for positioning knee components intra-operatively and in guiding the marking of bone before cutting and to guide cutting of the bone (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 knee 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 exact the same methods for design and verification and validation as the predicate device.

The following technological differences exist between the subject device software and the predicate device software.

The main difference between the subject device and previously cleared predicate device K251554 is the addition of the following **Zimmer Biomet** components in the software component of the subject device for the surgeon to select during the planning stage:

- Zimmer Persona® OsseoTi® Keel Tibia (K221479)
- Zimmer Persona® Cemented Keel Tibia (K221479)
- Zimmer Persona® PPS® Femur (K221479).

The subject software technology differences have been demonstrated that they do not affect the safety or effectiveness, or that they do not raise any different issues regarding 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 difference between the subject device hardware and the predicate device is the extension of compatibility of the SurgiCase Knee Guides and Models with additional **Zimmer Biomet** implant components:

- Zimmer Persona® OsseoTi® Keel Tibia (K221479)
- Zimmer Persona® Cemented Keel Tibia (K221479)
- Zimmer Persona® PPS® Femur (K221479).

Additionally, the **compatibility** with the following components **no longer on the market is removed:**

- Regenerex® Primary Tibial System
- Offset & Microplasty® Tibial Systems
- Maxim® Complete Knee System
- Ascent™ Total Knee System
- AGC® Complete Knee system
- Vanguard® SSK 360 Knee System
- Vanguard® SSK Revision Knee System

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 (no changes have been applied to the Hardware).

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 TKA Guide System is substantially equivalent to the predicate device.