July 5, 2022

Materialise NV
Jenny Jones
Global Quality and Regulatory Manager
Technologielaan 15
Leuven, 3001
Belgium

Re: K221337
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: May 6, 2022
Received: May 9, 2022

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 (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,

Ting Song, 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)*
K221337

Device Name
Materialise TKA Guide System

Indications for Use *(Describe)*
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, Vanguard® Complete Knee System, Vanguard® SSK 360, Vanguard® SSK Revision Knee System, Regenerex® Primary Tibial System, Offset & Microplasty® Tibial Systems, Maxim® Complete Knee System, Ascent™ Total Knee System, AGC® 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, Vanguard® SSK 360, Vanguard® SSK Revision Knee System, Regenerex® Primary Tibial System, Offset & Microplasty® Tibial Systems, Maxim® Complete Knee System, Ascent™ Total Knee System and AGC® 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, Vanguard® Complete Knee System, Vanguard® SSK 360, Vanguard® SSK Revision Knee System, Regenerex® Primary Tibial System, Offset & Microplasty® Tibial Systems, Maxim® Complete Knee System, Ascent™ Total Knee System, AGC® 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 Knee Guides 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 66 11
Fax number	+32 16 39 66 06
Principal contact person	Jenny Jones
Phone number	734-259-7017
Contact title	Global Quality Regulatory Manager
Contact e-mail address	Regulatory.Affairs@materialise.be
Additional contact person	Ilke Vanhaelen
Contact title	Device Development Engineer
Contact e-mail address	ilke.vanhaelen@materialise.be

Submission date

The date of the Traditional 510(k) submission is May 06, 2022.

Submission information

Trade Name	Materialise TKA Guide System
Common Name	Total knee replacement system with 3D planning software and patient specific instrumentation
Classification Name	Knee joint patellofemorotibial polymer /metal /polymer semi-constrained cemented prosthesis
Primary product code	JWH (21 CFR 888.3560)
Subsequent product codes	OIY, OOG, MBH

Predicate Devices

The predicate devices to which substantial equivalence is claimed:

Trade or proprietary or model name	*Materialise TKA Guide System*
510(k) number	K173445
Decision date	February 2, 2018
Classification product code	JWH (21 CFR 888.3560)
Subsequent product codes	MBH, OIY, OOG
Manufacturer	Materialise N.V.

The reference devices used to support a determination of substantial equivalence:

Trade or proprietary or model name	*Materialise PKA Guide System*
510(k) number	K202207
Decision date	October 02, 2020
Classification product code	HSX (21CFR888.3520)
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 pre-surgical TKA plan for a specific patient.
- 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

Note: indications for use differ from the predicate device because the compatible knee systems are different and the indications for use statement clarifies use of the models and software.

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

A detailed comparison shows the *Materialise TKA Guide System* is substantially equivalent in intended use, design, functionality, operating principles, materials, performance characteristics and the same fundamental scientific technology to the predicate device.

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.

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 K173445 is the addition of Ortho Development BKS CR, Ortho Development BKS PS, Ortho Development BKS TriMax CR and

Ortho Development BKS TriMax PS implants and instruments in the software component of the subject device for the surgeon to select during the planning stage.

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, raw materials, and performance characteristics to the predicate device K173445.

The main difference between the subject device and previously cleared predicate device K173445 includes: the addition of *Materialise TKA Guides and Models* that are compatible with the Ortho Development BKS CR, Ortho Development BKS PS, Ortho Development BKS TriMax CR and Ortho Development BKS TriMax PS implants and instruments. This resulted in the update of non-critical features of the *Materialise* TKA guides and models that will be used for this system.

Performance Data (non-clinical)

Hardware

Previous testing for 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 similar as that of the predicate device, and therefore previous simulated surgeries using rapid prototyped bone models and previous cadaver testing are considered applicable to the subject device.

Although no additional tests in comparison with the predicate device testing were required to support substantial equivalence, new biocompatibility, end-user cleaning, sterilization, and packaging testing have been done for other reasons as explained below.

- Biocompatibility re-evaluation according to ISO 10993-1:2018 was done. The subject device was shown to be non-cytotoxic, non-sensitizing, non-irritant, non-systematically toxic (acute) and non-pyrogenic.
- End-user cleaning re-evaluation was done on extended cleaning cycle specifications, including testing of both manual and automated cleaning cycle with both enzymatic and alkaline detergent on a new worst-case design. All samples passed the cleaning test, validating the updated cleaning parameters.
- Sterilization re-evaluation using an overkill method total cycle in accordance with ISO 17665-1:2006 on a new worst-case design. All samples passed the sterilization test, validating the applied sterilization parameters for the subject device.
- Packaging testing for the added packaging configuration according to ISO 11607-1:2019 according to ISTA 3A:2018 and simulated distribution in accordance with ASTM D4169-16. Samples passed the packaging testing, demonstrating that new packaging configuration meets approved requirements, allowing to effectively and safely ship the subject device, based on the validation performed on the specifications for the packaging applied.

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 TKA System* is substantial equivalent to the predicate device.