October 2, 2020

Materialise NV
Veerle Vanderheyden
Regulatory Affairs specialist
Technologielaan 15
Leuven, 3001
Belgium

Re: K202207
Trade/Device Name: Materialise PKA Guide System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX, OOG
Dated: August 4, 2020
Received: August 6, 2020

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,

Ting Song, Ph.D., R.A.C.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202207

Device Name
Materialise PKA Guide System

Indications for Use *(Describe)*
Hardware

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

The Materialise PKA Guides must be used in conjunction with the compatible prostheses families only: ZUK UNI, JOURNEY™ UNI, JOURNEY II UNI, JZ (Hybrid) UNI knee systems, Vanguard™ M Unicompartmental Knee System, Oxford® Partial Knee System and Persona® Partial Knee System.

The Zimmer Biomet Patient Specific Instruments are compatible for use with the Oxford® Partial Knee System as approved in P010014.

The Materialise PKA Guides are intended for single use only.

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

The Materialise PKA Models must be used in conjunction with the compatible prostheses families only: ZUK UNI, JOURNEY™ UNI, JOURNEY II UNI, JZ (Hybrid) UNI knee systems, Vanguard™ M Unicompartmental Knee System, Oxford® Partial Knee System and Persona® Partial Knee System.

The Zimmer Biomet Patient Specific Instruments are compatible for use with the Oxford® Partial Knee System as approved in P010014.

The Materialise PKA 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.

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1 510(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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Principal Contact person	Veerle Vanderheyden
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Additional contact person	Brecht Heyde
Contact title	Software product manager
Contact e-mail address	Brecht.heyde@materialise.be

Submission date

The date of the Traditional 510(k) submission is August 4, 2020.

Submission information

Device Name	*Materialise PKA Guide System*
Trade Name	*Materialise Knee Guides and Models* *SurgiCase Knee Planner* *Visionaire UNI Cutting Guides* *Visionaire UNI Bone Model* *Signature Guides* *Zimmer Patient Specific Instruments* *Zimmer Biomet Patient Specific Instruments.*
Common Name	3D planning software and patient specific instrumentation for knee replacement
Classification Name	Knee joint patellofemorotibial polymer /metal /polymer semi-constrained cemented prosthesis
Primary product code	HSX (21 CFR 888.3520)
Subsequent product codes	OOG

Predicate Device

The predicate device to which substantial equivalence is claimed:

Trade or proprietary or model name	*Materialise PKA Guide System*
510(k) number	K173970
Decision date	July 6, 2018
Classification product code	HSX (21 CFR 888.3520)
Subsequent product codes	OOG
Manufacturer	Materialise N.V.

Device Description

The *Materialise PKA guide system* is a medical device designed to be used to implant a partial knee prosthesis during partial knee arthroplasty surgical procedures.

The 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 PKA plan for a specific patient.

- A hardware component, branded as *Materialise PKA 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 PKA 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 tibia is delivered with the *Materialise PKA Guides*. The *Materialise PKA Guides and Models* assist in the intra-operative positioning of partial 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 PKA Guides and Models* must only be used within the intended use of the compatible components (510(k) cleared, legally marketed prosthesis).

Intended Use

Hardware

- Guides

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

The *Materialise PKA Guides* must be used in conjunction with the compatible prostheses families only: ZUK UNI, JOURNEY™ UNI, JOURNEY II UNI, JZ (Hybrid) UNI knee systems, Vanguard™ M Unicompartmental Knee System, Oxford® Partial Knee System and Persona® Partial Knee System.

The Zimmer Biomet Patient Specific Instruments are compatible for use with the Oxford® Partial Knee System as approved in P010014.

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

- Models

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

The *Materialise PKA Models* must be used in conjunction with the compatible prostheses families only: ZUK UNI, JOURNEY™ UNI, JOURNEY II UNI, JZ (Hybrid) UNI knee systems, Vanguard™ M Unicompartmental Knee System, Oxford® Partial Knee System and Persona® Partial Knee System.

The Zimmer Biomet Patient Specific Instruments are compatible for use with the Oxford® Partial Knee System as approved in P010014.

The *Materialise PKA* 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 PKA Guide System* generates a pre-surgical plan based on MRI 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 PKA Guides and Models* (models are optional) are designed and manufactured based on the approved pre-surgical plan. *Materialise PKA Guides* are patient specific templates which transfer the pre-operatively determined positioning of the chosen partial knee replacement components to the patient intra-operatively, assisting the surgeon in positioning and aligning the actual partial knee replacement components by guiding the marking of bone before cutting and to guide cutting of the bone. The models serve as a visual reference for the surgeon in the operating room.

Technological Characteristics

The *Materialise PKA Guide System* has an equivalent intended use and the same fundamental scientific technology as the predicate device. The subject device's software is intended simulation and planning of pre-operational intervention, and for positioning knee components, i.e. tibia and femur components (same as the predicate 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 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 main difference between the subject device and previously cleared predicate device K173970 is the addition of the Persona® Partial Knee (PPK) 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, materials and performance characteristics to the predicate device.

The main difference between the subject device and previously cleared predicate device K173970 include:

- The addition of *Materialise PKA Guides and Models* that are compatible with the Persona® Partial Knee (PPK) system. This resulted in the update of non-critical features of the PKA tibia guide that will be used for this system.

Performance Data (non-clinical)

Hardware

Previous testing for 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 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 and sterilization testing has been done for other reasons as explained in section below.

- Biocompatibility re-evaluation according to the new ISO 10993-1:2008 was done. The subject device was shown to be non-cytotoxic, non-sensitizing, non-irritant, non-systematically toxic (acute) and non-pyrogenic.
- Sterilization re-evaluation using an overkill method partial 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.

Software

New software validation/verification testing of the *SurgiCase Knee Planne*r was done in support of this pre-market notification in the form of end-user evaluations.

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 PKA Guide System* is substantial equivalent to the predicate device. The *Materialise PKA Guide System* will be manufactured in compliance with FDA (CFR 820 & Part 11) and ISO quality system (13485) requirements.