July 6, 2018

Materialise NV
Oliver Clemens
Regulatory Officer
Technologielaan 15
Leuven, 3001 Be

Re: K173970
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: December 29, 2017
Received: December 29, 2017

Dear Oliver 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 Part 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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vincent J. Devlin -S
for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173970

Device Name
Materialise PKA Guide System

Indications for Use *(Describe)*
The Materialise PKA Guide System is intended to be used as a surgical instrument to assist in the positioning of Partial Knee Replacement components intra-operatively and in guiding the marking of bone before cutting and to guide cutting of the bone.

The Materialise PKA Guide System is to be used with ZUK UNI, JOURNEY™ UNI, JOURNEY II UNI, JZ (Hybrid) UNI knee systems, Vanguard™ M Unicompartmental Knee System and Oxford® Partial Knee System prostheses families only.

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.

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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"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 62 80
Fax number	+32 16 39 66 06
Principal Contact person	Oliver Clemens
Contact title	Regulatory Affairs Officer
Contact e-mail address	Regulatory.Affairs@materialise.be
Additional contact person	Wim Claassen
Contact title	Portfolio Manager
Contact e-mail address	Wim.Claassen@materialise.be

Submission date

The date of the Traditional 510(k) submission is December 21, 2017.

Submission information

Device name	*Materialise PKA Guide System*
Trade Name	*Materialise PKA Planner* *Materialise PKA Guide* *SurgiCase Planner* *Visionaire UNI cutting guides* *Signature Planner* *Signature Guides* *Zimmer Patient Specific Instruments Planner* *Zimmer Patient Specific Instruments*
Common Name	Knee prosthesis
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 Devices

The predicate devices to which substantial equivalence is claimed:

Trade or proprietary or model name	*Materialise PKA Guide System*
510(k) number	K172650
Decision date	November 20, 2017
Classification product code	HSX (21 CFR 888.3520)
Subsequent product codes	OOG
Manufacturer	Materialise N.V.

Trade or proprietary or model name	*Signature Personalized Patient Care System*
510(k) number	K110415
Decision date	May 16, 2011
Classification product code	HRY (21 CFR 888.3530)
Subsequent product codes	JWH, MBH, OIY, OOG
Manufacturer	Materialise N.V.

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.

Device Description

Materialise PKA Guides are patient-specific medical devices that are designed to be used to implant partial knee prosthesis.

The *Materialise PKA Guides* must only be used in conjunction with the 510(k) cleared, legally marketed prosthesis. Consult the prosthesis labeling and instructions for use for specific patient indications, contraindications, associated

risks, information for use, warnings and precautions. *Materialise PKA Guides* is an instrument set containing a femur and/or tibia template(s) and bone models.

Intended Use

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

The *Materialise PKA Guide System* is to be used with ZUK UNI, JOURNEY™ UNI, JOURNEY II UNI, JZ (Hybrid) UNI knee systems, Vanguard™ M Unicompartmental Knee System and Oxford® Partial Knee System prostheses families only.

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.

Functioning of the Device

The *Materialise PKA Guide System* generates a pre-surgical plan based on MRI images using the *Materialise PKA 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 PKA Guides* 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.

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 devices. The main difference between the subject device and previously cleared predicate device K172650 is the addition of the Oxford and Vanguard M implants in the Planner software for the surgeon to select during the planning stage. The software algorithm was extended with an Oxford specific planning algorithm which was previously cleared as part of the software component of predicate device K110415. Furthermore, the medical coordinate system and clinical relevant landmarks for the PKA Oxford specific planning algorithm were aligned with those of the TKA procedure as cleared in predicate device K173445. The changes do not affect the safety and effectiveness of the devices.

Performance Data

No new testing of the Materialise PKA Guides was done in support of this pre-market notification. Previous testing for biocompatibility, sterility, cleaning, debris and dimensional stability 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 the same as that of the predicate *Signature Personalized Patient Care System* (K110415) and therefore previous cadaver testing on predicate device K110415 is considered applicable to the subject device. New software validation/verification testing of the Materialise PKA Planner was done in support of this pre-market notification in the form of usability evaluations.

Summary

The characteristics that determine the functionality and performance of the subject device, the *Materialise PKA Guide* System are substantially equivalent to the devices cleared under K172650 and K110415. The non-clinical testing indicates that the subject device is as safe, as effective, and performs as well as the predicates. The *Materialise PKA Guide System* will be manufactured in compliance with FDA (CFR 820 & Part 11) and ISO quality system (9000 and 13485) requirements.