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

February 2, 2018

Re: K173445
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, OOG, OIY, MBH
Dated: November 6, 2017
Received: November 6, 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Katherine D. Kavlock -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)*
K173445

Device Name
Materialise TKA Guide System

Indications for Use *(Describe)*

Pin Placement Guides

The Materialise TKA Guide System is 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 Guide System 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 Flex fixed bearing, Zimmer Persona™ CR fixed bearing, Zimmer Persona™ PS fixed bearing, Zimmer Persona™ Trabecular Metal™, 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, Consensus Knee System, Lima Physica PS System Knee System, Lima Physica CR Knee System, Lima Physica KR Knee System, Omni Apex CR and Omni Apex PS prostheses families only.

The Materialise TKA Guides are intended for single use only.

Cut-Through Guides

The Materialise TKA Guide System is 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 Guide System must be used in conjunction with 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.

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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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 October 31, 2017

Submission information

Trade Name	*Materialise TKA Guide System*
Common Name	Knee prosthesis
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	K162273
Decision date	November 7, 2016
Classification product code	JWH (21 CFR 888.3560)
Subsequent product codes	MBH, OIY, 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	*Zimmer Patient Specific Instruments System*
510(k) number	K140027
Decision date	May 22, 2014
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	*Kuvia3D*
510(k) number	K161559
Decision date	June 23rd, 2016
Classification product code	LLZ (21 CFR 892.2050)
Manufacturer	4QIMAGING, LLC DBA QMETRICS

Device Description

Materialise TKA Guides are patient-specific medical devices that are designed to be used to implant total knee prosthesis during total knee arthroplasty surgical procedures.

The Materialise TKA Guides must only 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 Flex fixed bearing, *Zimmer Persona™ CR* fixed bearing, *Zimmer Persona™* PS fixed bearing, *Zimmer Persona ™ Trabecular Metal ™*, 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, Consensus Knee System, Lima Physica PS System Knee System, Lima Physica CR Knee System, Lima Physica KR Knee System, Omni Apex CR and Omni Apex PS total knee prostheses. Consult the prosthesis labeling and instructions for use for specific patient indications, contraindications, associated risks, information for use, warnings and precautions. Materialise TKA Guides is an instrument set containing a femur and/or tibia template(s).

Intended Use

Pin Placement Guides

The Materialise TKA Guide System is 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 Guide System 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 Flex fixed bearing, *Zimmer Persona™ CR* fixed bearing, *Zimmer Persona™* PS fixed bearing, *Zimmer Persona™ Trabecular Metal™*, 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, Consensus Knee System, Lima Physica PS System Knee System, Lima Physica CR Knee System, Lima Physica KR Knee System, Omni Apex CR and Omni Apex PS prostheses families only.

The Materialise TKA Guides are intended for single use only.

Cut-Through Guides

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The Materialise TKA Guides are intended for single use only.

Functioning of the Device

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

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 device.

Performance Data

Materialise TKA Guide System was validated though non-clinical tests to verify the system is adequate to perform as intended and to determine substantial equivalence. Previous testing for biocompatibility, sterility, cleaning, debris, dimensional stability are applicable to the subject device and demonstrate substantial equivalence with the predicate devices. An updated packaging test is performed. Previous testing that verified that the accuracy and performance of the system is adequate to perform as intended is applicable to the subject device.

Summary

The characteristics that determine the functionality and performance of the subject device, the *Materialise TKA Guide* System are substantially equivalent to the device cleared under K162273, K110415 and K140027. The non-clinical testing indicates that the subject device is as safe, as effective, and performs as well as the predicate. The *Materialise TKA Guide System* will be manufactured in compliance with FDA (CFR 820 & Part 11) and ISO quality system (9000 and 13485) requirements.