DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Materialise N.V.
Laurel Berzanskis
Regulatory Affairs Officer
Technologielann 15
3001 Leuven
Belgium

August 10, 2015

Re: K150928
Trade/Device Name: Materialise TKA Guide System (Materialise TKA Planner, Materialise TKA Guides)
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: July 6, 2015
Received: July 10, 2014

Dear Laurel Berzanskis:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K150928

Device Name: **Materialise TKA Guide System** (Materialise TKA Planner, Materialise TKA Guides)

Indications for Use:

The Materialise TKA Guide System is intended to be used as a surgical instrument to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The Materialise TKA Guide System is to be used 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 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, and AGC® Complete Knee system, and Consensus Knee System prostheses families only.

The Materialise TKA Guides are intended for single use only.

Prescription Use _ X ____ AND/OR Over-The-Counter Use __ _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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 74 45 37
Fax number	+32 16 39 66 06
Principal Contact person	Laurel Berzanskis
Contact title	Regulatory Affairs Officer
Contact e-mail address	Regulatory.Affairs@materialise.be
Additional contact person	Wim Claassen
Contact title	Product Manager
Contact e-mail address	Wim.Claassen@materialise.be

Submission date

The date of the Traditional 510(k) submission is April 3, 2015.

Submission information

Trade Name	*Materialise TKA Planner* *Materialise TKA Guide*
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 **primary** predicate devices to which substantial equivalence is claimed:

Trade or proprietary or model name	*Zimmer* Patient Specific Instruments System 5.4
510(k) number	K133162
Decision date	February 25th, 2014

Classification product code	JWH (21 CFR 888.3560)
Subsequent product codes	MBH, OIY, OOG
Manufacturer	Materialise N.V.

The **secondary** predicate device to which substantial equivalence is claimed:

Trade or proprietary or model name	Signature Personalized Patient Care System (Signature Planner; Signature guides)
510(k) number	K102795
Decision date	February 2nd, 2011
Classification product code	JWH (21 CFR 888.3560)
Subsequent product codes	MBH, OIY, OOG
Manufacturer	Materialise N.V.

Device Description

Materialise TKA Guides are patient-specific medical devices that are designed to be used to implant the following knee prostheses:

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, and AGC® Complete Knee system, and Consensus Knee System.

The Materialise TKA Guides must only be used in conjunction with the implants listed above. 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

The Materialise TKA Guide System is intended to be used as a surgical instrument to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The Materialise TKA Guide System is to be used 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 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, and AGC® Complete Knee system, and Consensus Knee System prostheses families only.

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 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 and marking drill locations.

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 primary predicate and secondary predicate devices, however offers a web based software application rather than a desktop application, and extends the compatible implant families to Consensus implants cleared under K945589, K932837, K143725, K110950, K102927, K001456, K983004, K962215, and K954818.

Performance Data

Materialise TKA Guide System was validated though non-clinical tests using saw bones to verify the system is adequate to perform as intended and to determine substantial equivalence. 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. Testing verified that the accuracy and performance of the system is adequate to perform as intended. Cadaver testing validated the use of the subject device for use in total knee replacement and demonstrated equivalent product performance as the existing predicate devices (K102795 and K133162).

Summary

The characteristics that determine the functionality and performance of the subject device, the Materialise TKA Guide System are substantially equivalent to the devices cleared under K133162 and K102795. The non-clinical testing indicates that the subject device is as safe, as effective, and performs as well as the predicates. The Materialise TKA Guide System will be manufactured in compliance with FDA (CFR 820 & Part 11) and ISO quality system (9000 and 13485) requirements.