November 20, 2017

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

Re: K172650
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: September 5, 2017
Received: September 5, 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,

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)*
K172650

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 provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The Materialise PKA Guide System is to be used with ZUK UNI, JOURNEY™ UNI, JOURNEY II UNI, JZ (Hybrid) UNI knee systems prostheses families only.

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.**

## 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 August 25, 2017

**Submission information**

| | |
|---|---|
| *Trade Name* | *Materialise PKA Planner*<br>*Materialise PKA Guide*<br>Visionaire UNI cutting guides |
| *Common Name* | Knee prosthes is |
| *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 **primary** predicate devices to which substantial equivalence is claimed:

Materialise N.V.

| | |
|---|---|
| *Trade or proprietary or model name* | *Zimmer* Patient Specific Instruments System 3.0 |
| *510(k) number* | K112301 |
| *Decision date* | January 6th, 2012 |
| *Classification product code* | HSX (21 CFR 888.3520) |
| *Subsequent product codes* | OOG |
| *Manufacturer* | Materialise N.V. |

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

| | |
|---|---|
| *Trade or proprietary or model name* | Materialise TKA Guide System |
| *510(k) number* | K162273 |
| *Decision date* | November 7th, 2016 |
| *Classification product code* | JWH (21 CFR 888.3560) |
| *Subsequent product codes* | MBH, OIY, OOG |
| *Manufacturer* | Materialise N.V. |

The reference device for the cartilage color map functionality:

| | |
|---|---|
| *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 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 provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The Materialise PKA Guide System is to be used with ZUK UNI, JOURNEY™ UNI, JOURNEY II UNI, JZ (Hybrid) UNI knee systems prostheses families only.

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 primary predicate and secondary predicate devices.

**Performance Data**

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. 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 *Zimmer* Patient Specific Instruments System (K112301) and therefore previous cadaver testing on predicate device K112301 is considered applicable to the subject device.

**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 K112301 and K162273. 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.