K102795 (1/3)

FEB - 2 2011

# 510(k) Summary

## *Submitter information*

| | |
|---|---|
| *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 |
| *Contact name* | Alexandra Razzhivina |
| *Contact title* | Regulatory affairs officer |
| *Contact e-mail address* | alexandra.razzhivina@materialise.be |

## *Submission date*

The date of the Traditional 510(k) submission is 24th September 2010.

## *Submission information*

| | |
|---|---|
| *Trade Name* | Signature™ Planner<br>Signature™ guides |
| *Common Name* | knee prosthesis |
| *Classification Name* | - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis<br>-Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis |
| *Product code* | JWH/OIY (21 CFR § 888.3560), MBH (21 CFR § 888.3565), OOG |

## *Predicate devices*

| **Predicate Device** | |
|---|---|
| *Trade or proprietary or model name* | SurgiCase |
| *510(k) number* | K073449 |
| *Decision date* | 04/16/2008 |
| *Product code* | LLZ |
| *Manufacturer* | Materialise N.V. |

| Predicate Device | |
|---|---|
| *Trade or proprietary or model name* | Zimmer Patient Specific Instruments System 2.0 |
| *510(k) number* | K093533 |
| *Decision date* | 02/17/2010 |
| *Product code* | JWH, MBH |
| *Manufacturer* | Materialise N.V. |

## *Device Information*

### Description of the device

Signature TM Personalized Patient Care System consists of a software component, **Signature™ Planner** and a hardware component, **Signature™ guides** and is designed to assist the surgeon in the placement of total knee replacement components.

### Functioning of the device

Signature TM Personalized Patient Care System generates a pre-surgical plan based on MRI or CT imaging data using the **Signature™ Planner** (software component). The software is then used pre-operatively by a qualified surgeon to inspect, fine-tune and approve the pre-surgical plan. Next, **Signature™ guides** are designed and manufactured based on the approved pre-surgical plan. **Signature™ guides** are patient specific templates that transfer the pre-operatively determined pin locations for positioning of the total knee replacement components to the patient intra-operatively. The surgical guides are used to accurately place the guide pins used to position the cutting blocks.

## *Intended use*

**Signature™ Personalized Patient Care 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 **Signature Personalized Patient Care System** can be used with the following Biomet knee systems and their respective components: 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.

The **Signature™ guides** are intended for single use only.

## *Summary of technological characteristics*

Device comparison showed that the proposed device is substantially equivalent to the predicate devices, in that the device materials are identical to the predicate; and, like the predicate device, the subject device is matched to the patient using software.

## *Performance data*

### Non-clinical tests

The Signature™ Planner software has been validated for its intended use to determine substantial equivalence to the predicate devices.

Accuracy performance testing by means of cadaveric trials, and guide deformation verification after sterilization was performed to determine substantial equivalence. Testing verified that the accuracy and performance of the system is adequate to perform as intended.

### Clinical data

Not applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Materialise N.V.
% Ms. Alexandra Razzhivina
Technologielaan 15
3001 Leuven, Belgium

FEB - 2 2011

Re: K102795
Trade/Device Name: Signature™ Personalized Patient Care System (Signature™ Guides, Signature™ Planner)
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, MBH, OOG
Dated: December 23, 2010
Received: December 27, 2010

Dear Ms. Razzhivina:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for

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

Enclosure

**510(k) Number K102795:**

**Device Name:** Signature™ Personalized Patient Care System (**Signature™ guides, Signature™ Planner**)

**Indications for Use:**

**Signature™ Personalized Patient Care 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 **Signature™ Personalized Patient Care System** can be used with the following Biomet knee systems and their respective components: 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.

The **Signature™ 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)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices



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