



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

Materialise NV
Mr. Oliver Clemens
Regulatory Officer
Technologielaan 15
3001 Leuven
BELGIUM

October 27, 2015

Re: K150780

Trade/Device Name: Acetabular Cup Orientation System
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PLW, JDI
Dated: September 21, 2015
Received: September 24, 2015

Dear Mr. 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 Parts 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)
K150780

Device Name
Acetabular Cup Orientation System

Indications for Use (Describe)

The Acetabular Cup Orientation (ACO) System is intended to be used as a surgical instrument to place a visual reference k-wire alignment pin to assist in the intra-operative orientation of acetabular cup components used with total hip arthroplasty procedures. The system utilizes anatomic landmarks of the pelvis that are clearly identifiable on pre-operative CT imaging scans.

The ACO System can be used with any 510(k) cleared, legally marketed, hemispherical acetabular cup implant system for primary Total Hip Arthroplasty (THA) and its respective compatible components, with the additional conditions listed below:

- Spherically shaped, symmetrical acetabular cups.
- Without protrusions for fixation such as spikes, threads, pegs, flanges or similar protruding elements.
- Cups with smooth outer surface or uniform coating.
- The central axis of the cup matches the direction of impaction; the inner and outer spherical surface of the cup have the same central axis.
- Cups have an apex hole to connect an impactor.
- Allowed deviations from a hemispherical cup shape (as long as the conditions stated above are fulfilled):
 - o Cups with a very slightly flattened dome.
 - o Cups with one or more holes for fixation with screws.

The ACO guides can only be used with hip systems that include reamers and impactors with straight handles.

The ACO guides can be used for posterior approach (Moore, also referred to as the 'Southern approach'), postero-lateral approach (Marcy-Fletcher), lateral approach (Hardinge) and antero-lateral approach (Watson-Jones).

The ACO 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.

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510(k) Summary

Submitter information

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<i>Contact name</i>	Oliver Clemens
<i>Contact title</i>	Regulatory Officer
<i>Contact e-mail address</i>	regulatory.affairs@materialise.be

Submission date

The date of the Traditional 510(k) submission is 20 March, 2015.

Submission information

<i>Trade Name</i>	Acetabular Cup Orientation System
<i>Common Name</i>	Hip joint metal/polymer semi-constrained cemented prosthesis
<i>Primary product codes</i>	PLW (21 CFR 888.3350)

Predicate devices

Predicate Device	
<i>Trade or proprietary or model name</i>	Signature™ Personalized Patient Care System – Acetabular Guide System
<i>510(k) number</i>	K111863
<i>Decision date</i>	15 June 2012
<i>Product code</i>	JDI
<i>Manufacturer</i>	Materialise N.V.

Device Information

Description of the device

The **Acetabular Cup Orientation System** consists of a software component, the **Acetabular Cup Orientation Planner** and a hardware component, the **Acetabular Cup Orientation guides** and is designed to assist the surgeon in the pre-op visualization and planning of the acetabular cup

orientation and to assist intra-operatively in the orientation of the acetabular cup implant by placement of a visual reference pin.

The **Acetabular Cup Orientation System** is designed for cup orientation guidance within total hip arthroplasty surgery (THA).

Functioning of the device

The **Acetabular Cup Orientation System** generates a pre-surgical plan based on medical imaging data using the **Acetabular Cup Orientation 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, **Acetabular Cup Orientation guides** are designed and manufactured based on the approved pre-surgical plan. **Acetabular Cup Orientation guides** are patient specific templates that transfer the pre-operatively determined pin location and the planned acetabular cup orientation to the patient intra-operatively.

Intended use

The **Acetabular Cup Orientation (ACO) System** is intended to be used as a surgical instrument to place a visual reference k-wire alignment pin to assist in the intra-operative orientation of acetabular cup components used with total hip arthroplasty procedures. The system utilizes anatomic landmarks of the pelvis that are clearly identifiable on pre-operative CT imaging scans.

The **ACO System** can be used with any 510(k) cleared, legally marketed, hemispherical acetabular cup implant systems for primary Total Hip Arthroplasty (THA) and its respective compatible components, with the additional conditions listed below:

- Spherically shaped, symmetrical acetabular cups.
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The ACO guides are intended for single use only.

Summary of technological characteristics

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate devices.

- Both subject device and predicate device are to be used as a surgical instrument to assist the surgeon in pre-operative planning and evaluation of surgical treatment options
- The guides of the subject and predicate devices are intended to assist in the intra-operative orientation of acetabular cup components
- The guides of the subject and predicate devices are designed and manufactured from reconstructed three-dimensional models of the patient's anatomy
- The guides of the subject and predicate devices are made of the same material and follow the same manufacturing process
- The software component of the subject and predicate device are intended for use as medical device for Materialise and a surgeon for pre-surgical simulation and evaluation of surgical treatment options, which includes transferring, visualizing, measuring, annotating and editing medical data

Performance data

Non-clinical tests

Acetabular Cup Orientation Guides were validated through non-clinical studies using cadaver specimens: On a series of cadaveric specimens, Acetabular Cup Orientation guides were designed and applied according to a pre-operative plan. The planned versus achieved orientation of acetabular component were compared. The deviations between planned versus achieved orientation of the acetabular cup component were within the preset acceptance criteria.

Other tests performed: Biocompatibility test, sterility test, sterilization dimensional stability test, cleaning validation test, load bench test, drop test, visible debris test, skiving prevention and packaging and shipment test were performed to assess the safety and effectiveness of the Acetabular Cup Orientation Guides. Testing verified that the accuracy and performance of the device is adequate to perform as intended.

Clinical data

Clinical testing was not performed.

Summary

The data presented in the 510(k) submission demonstrates that the subject device is substantially equivalent to the predicate device.