**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 18, 2017

Medacta International SA
% Elizabeth Rose
Manager, Regulatory Affairs
Mapi Usa, Inc
2343 Alexandria Drive
Suite 100
Lexington, Kentucky 40504

Re: K170149
Trade/Device Name: 3DMetal Tibial Cones
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
Dated: July 3, 2017
Received: July 3, 2017

Dear Elizabeth Rose:

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" (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.

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,

Mark N. Melkerson -S

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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K170149

Device Name
3DMetal Tibial Cones

Indications for Use *(Describe)*
The 3DMetal Tibial Cones are indicated for use with the GMK Revision and GMK Hinge knee systems, as well as the GMK tibial extension stems and offsets.
Specific indications are as follows:
• Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
• Post traumatic loss of joint configuration.
• Considerable loss of function of the knee joint.
• High-grade joint destruction requiring additional stabilization and reconstruction of bone defects.
• Primary implantation failure.
• Former revision arthroplasty.

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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# 3.0 510(k) Summary

## I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager
Date Prepared: January 13, 2017
Date Revised: July 3, 2017

## II. Device

| | |
|---|---|
| Device Proprietary Name: | 3DMetal Tibial Cones |
| Common or Usual Name: | Total Knee Prosthesis |
| Classification Name: | Knee joint, patellofemorotibial polymer/metal/polymer semi constrained cemented prosthesis |
| Regulation Number: | 21 CFR 888.3560 |
| Product Code: | JWH |
| Device Classification | 2 |

## III. Predicate Device

Substantial equivalence is claimed to the following devices:
Primary Predicate:

- Trabecular Metal Tibial Cone Augments, K102896, Zimmer Trabecular Metal Technology
- Regenerex Porous Titanium Sleeve Augments, K072336, Biomet Manufacturing Corp.

Reference Predicate

- GMK Total Knee System (also referred to as GMK Primary), K090988, Medacta International SA
- GMK Total Knee System-Revision (also referred to as GMK Revision), K102437, Medacta International SA
- GMK Hinge, K130299, Medacta International SA
- Delta TT Acetabular System, K141395, Limacorporate S.p.A.

## IV. Device Description

The 3DMetal Tibial Cones are implantable devices to be used as fillers in cases of severe bone deficiency. The subject devices are to be cemented to the GMK Revision and GMK Hinge systems' tibial trays. The subject devices have a full-density layer that prevents cement occluding the pores of the external layer.

The purpose of this submission is to gain clearance for the tibial cones available in centred and eccentric versions. The tibial cones are available in sizes XS, S, M, and L with heights of 20 mm and 25 mm.

The subject devices are intended to be used with the cleared indications for use and the tibial trays of Medacta's GMK Revision (K102437) and GMK Hinge (K130299) systems.

The 3DMetal Tibial Cones are manufactured with titanium alloy substrate, which is identical to predicate devices Regenerex Porous Titanium Sleeve Augments (K072336). However the subject devices' material is processed using electron beam melting (EBM) similar to the material of referenced device Delta TT Acetabular System (K141395).

## V. Indications for Use

The 3DMetal Tibial Cones are indicated for use with the GMK Revision and GMK Hinge knee systems, as well as the GMK tibial extension stems and offsets.
Specific indications are as follows:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
- Post traumatic loss of joint configuration.
- Considerable loss of function of the knee joint.
- High-grade joint destruction requiring additional stabilization and reconstruction of bone defects.
- Primary implantation failure.
- Former revision arthroplasty.

## VI. Comparison of Technological Characteristics

The 3DMetal Tibial Cones and the predicate devices share the following characteristics:

- Indications for Use
- Materials
- Packaging
- Design
- Use with tibial trays
- Sterile
- Sizes

The 3DMetal Tibial Cones are technologically different from the predicate devices as follows:

- Heights available
- Manufacturing Process

Biocompatibility testing conducted on the predicate and reference devices for the same material, supports the biological safety of the 3DMetal Tibial Cones. Additional biocompatibility testing was deemed unnecessary because the materials and manufacturing process are identical to the predicate devices described below and meet ISO 5832-3:1996 Implants For Surgery – Metallic Materials – Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy and ASTM F2924-12a Standard Specification For Additive Manufacturing Titanium-6 Aluminum-4 Vanadium With Powder Bed Fusion.

A comparison of the subject and predicate devices is provided in the table below.

Technological comparison

| **Parameters** | **3DMetal Tibial Cones (Subject Device)** | **Trabecular Metal Tibial Cone Augments K102896 (Predicate Device)** | **Regenerex Porous Titanium Sleeve Augments K072336 (Predicate Device)** |
|---|---|---|---|
| Design/Types | Cemented to cone of tibial tray; Centred and Eccentric | Cemented to cone of tibial tray; Full and Stepped | Cemented to cone of tibial tray |
| Material | Titanium Alloy | Tantalum | Titanium Alloy |
| Manufacturing Process | Electron Beam Melting | Additive Manufacturing | Chemical Vapor Deposition |
| Sizes | Sizes XS, S, M, L | Sizes XS, S, M, L | Sizes XS, S, M, L |
| Heights | 20 mm, 25 mm | 15 mm, 30 mm | 25mm, 40mm |
| Compatibility with implant system | GMK Revision and GMK Hinge | NexGen Complete Knee Solution, Legacy LCCK and Rotating Hinge Knee Systems | Vanguard SSK Revision Knee System |
| Device usage | Single Use | Single Use | Single Use |
| Shelf Life | 5 years | 5 years | 5 years |
| Biocompatibility | Implant with permanent >30 day (Equivalency determined) | Implant with permanent >30 day | Implant with permanent >30 day |
| Sterilization | Gamma | Gamma | Gamma |
| Packaging | Individual packaging | Individual packaging | Individual packaging |

*Discussion*
As seen above, the differences between the subject and predicate devices are that the subject devices have different heights than the predicate devices. Although the subject devices and predicate devices are made of titanium alloy, the manufacturing process method is different because the subject devices use electron beam melting to process the titanium. This technological difference does not raise new questions of safety or effectiveness and a comparison evaluation shows there are no new risks associated with the subject devices design.

## VII. Performance Data

Based on the risk analysis and pre-submission submitted to FDA to review testing protocols, testing was conducted to written protocols with acceptance criteria that were based on standards and FDA guidance documents. The following mechanical tests are being provided in support of a substantial equivalence determination:

Non-Clinical Studies

- Dynamic Fatigue Test: ASTM F1800-12 Standard Test Method For Cyclic Fatigue Testing Of Metal Tibial Tray Components Of Total Knee Joint Replacements
- Characterization Test
    - Shear Testing: ASTM F1044-05 (Reapproved 2011) Standard Test Method For Shear Testing of Calcium Phosphate Coatings And Metallic Coatings
    - Shear Fatigue Testing: ASTM F1160-14 Standard Test Method For Shear and Bending Fatigue Testing of Calcium Phosphate And Metallic Medical And Composite Calcium Phosphate/Metallic Coatings
    - Tensile Testing: ASTM F1147-05 (Reapproved 2011) Standard Test Method For Tension Testing of Calcium Phosphate And Metal Coatings
    - Stereological Evaluation: ASTM F1854-09 Standard Test Method For Stereological Evaluation Of Porous Coatings On Medical Implants
- Pyrogenicity
    - Medacta uses both the Bacterial Endotoxin Test (LAL test) according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and the Pyrogen Test according to USP chapter <151> for pyrogenicity determination.
    - Medacta has no intentions of labeling the subject devices as non-pyrogenic or pyrogen free.

Clinical Studies

- No clinical studies were conducted.

## VIII. Conclusion

The information provided above supports that the 3DMetal Tibial Cones are as safe and effective as the predicate devices. The subject devices are manufactured using the Electron Beam Melting (EBM) process in with titanium alloy, as compared to the predicate devices, does not raise any new questions of safety and effectiveness. Therefore, it is concluded that the 3DMetal Tibial Cones are substantially equivalent to the predicate devices.