March 13, 2020

Medacta International SA
% Chris Lussier
Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K200075
Trade/Device Name: 3DMetal Diaphyseal Femoral 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: January 13, 2020
Received: January 14, 2020

Dear Chris Lussier:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ting Song
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K200075

Device Name
3DMetal Diaphyseal Femoral Cones

Indications for Use *(Describe)*
The 3DMetal Femoral Cones are indicated for use with the GMK Revision and GMK Hinge knee systems, as well as the GMK femoral 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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2.0 510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Director of Quality and Regulatory, Medacta USA
Date Prepared: January 13, 2020

II. Device

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

III. Predicate Device

Substantial equivalence is claimed to the following device:

- Trabecular Metal™ Femoral Cone Augments, K103517, Zimmer Trabecular Metal Technology, Inc

In addition, the following Reference device is cited within the submission:

- 3DMetal Tibial Cones (K170149), Medacta International SA

IV. Device Description

The 3DMetal Diaphyseal Femoral Cones are sterile implantable devices intended to be used in the diaphyseal side of the femoral component in order to fill and reconstruct large bone deficiencies and cavitary defects in the diaphysis of the distal femur.

The subject devices are available in four different sizes and they are to be cemented to the extension stem used in GMK Revision and GMK Hinge systems in Total Knee Arthtroplasty procedures.

Analogously to the reference devices, the 3DMetal Diaphyseal Femoral Cones are manufactured using Electron Beam Melting (EBM) process with titanium alloy powder.

V. Indications for Use

The 3DMetal Femoral Cones are indicated for use with the GMK Revision and GMK Hinge knee systems, as well as the GMK femoral 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 Diaphyseal Femoral Cones and the predicate Trabecular Metal Femoral Cone Augments share the following characteristics:

- shape;
- porosity of trabecular layer;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The 3DMetal Diaphyseal Femoral Cones differ from the predicate devices as follow:

- sizes
- material

Discussion

Medacta International SA has not made any change to the intended use, shape, device usage, biocompatibility, sterility, shelf life, and packaging of the subject devices respect to the predicate devices.

The slight difference in sizes between the subject and the predicate devices does not raise new question of safety or effectiveness as demonstrated by design validation testing.

The different material of the 3DMetal Diaphyseal Femoral Cones with respect to the predicate devices, do not compromise device safety and performance since the material of the subject

device, Ti6Al4V is commonly used for implantable medical devices. Additionally, the subject device material and manufacturing process are shared with the reference devices, 3DMetal Tibial Cones (K170149).
The comparison of technological characteristics and performance data provided within this submission, shows that there are no new risks associated with the subject devices design, and supports the substantial equivalence of the 3DMetal Diaphyseal Femoral Cones implants to the identified predicate devices.

VII. Performance Data

Based on the risk analysis, design validation and characterization testing were conducted to written protocols. The following validation and tests are being provided in support of the substantial equivalence determination:

Non-Clinical Studies

- *DESIGN VALIDATION*
  - 3DMetal Diaphyseal Femoral Cones Design Rationale Shape, Dimension and Range of Product. *Test Report B2 + Addendum.*

- *CHARACTERIZATION TESTING*
  - 3DMetal Diaphyseal Femoral Cones Dynamic Fatigue Test according to IL 07.09.5173 rev.0 and Report 00812-009932-1. *Test report B1*
  - 3DMetal Diaphyseal Femoral Cones Stereological evaluation according to ASTM F1854-15 and Test Report 00812-009932-2. *Test report B3*

- *PYROGENICITY:*
  - Bacterial endotoxin test (LAL test) according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>)
  - Pyrogen test according to USP chapter <151> for pyrogenicity determination
  - The subject devices are not labeled as non-pyrogenic or pyrogen free.

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the 3DMetal Diaphyseal Femoral Cones are as safe and effective as the predicate devices. Therefore, it is concluded that the 3DMetal Diaphyseal Femoral Cones are substantially equivalent to the predicate device.