August 23, 2022

Medacta International S.A.
℅ Chris Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K221850
Trade/Device Name: GMK 3D Metal Tibial Tray
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: June 24, 2022
Received: June 27, 2022

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,

For: Ting Song, Ph.D., R.A.C.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221850

Device Name
GMK 3D Metal Tibial Tray

Indications for Use *(Describe)*
The GMK® knee prosthesis is designed for cemented application in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.

The GMK 3D Metal® Tibial Baseplate is indicated for cementless or cemented application if there is evidence of sufficient sound bone to seat and support the components.

This knee replacement system is indicated in the following cases:
• Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis
• Collagen disorders, and avascular necrosis of the femoral condyle
• Post traumatic loss of joint configuration
• Primary implantation failure

Tibial wedges cemented are to be attached to the tibial baseplate with both the fixing cylinders and bone cement. The screwed tibial augments are for screwed fixation to the tibial baseplate. In case a semi-constrained liner is used, an extension stem must be implanted both on the tibial and on the femoral components. In case a GMK Revision or GMK Sphere Revision tibial tray is used, an extension stem must be implanted.

It is not possible to implant tibial wedges and extension stems with the GMK 3D Metal® Tibial Baseplate.

Limitations for use for GMK SPHERE/GMK SPHERIKA used with kinematic alignment

GMK® Sphere and GMK® SpheriKA can be implanted in kinematic alignment. In this case, this knee replacement system is indicated for:
• Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis
• Collagen disorders, and/or avascular necrosis of the femoral condyle
• Moderate valgus, varus, or flexion deformities

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. Submitter

Medacta International SA
Strada Regina
6874 Castel San Pietro (CH)
Switzerland
Phone (+41) 91 696 60 60
Fax (+41) 91 696 60 66

Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director Quality, Regulatory, and Clinical Research, Medacta USA
Date Prepared: June 24, 2022
Date Revised: August 23, 2022

II. Device

Device Proprietary Name:	GMK 3D Metal Tibial Tray
Common or Usual Name:	Total Knee Joint Replacement
Classification Name:	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Primary Product Code	MBH
Secondary Product Code:	JWH
Regulation Number:	21 CFR 888.3565, 21 CFR 888.3560
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary predicate device:

- Triathlon Tritanium Tibia Baseplate, Stryker, K123486

Additional predicate devices:

- GMK Total Knee System, K090988, Medacta International SA
- GMK Sphere, K121416, Medacta International SA
- GMK Spherika Femurs and Fixed Tibial Trays Plus, K211004, Medacta International SA
- Triathlon Total Knee System, K201343, Howmedica Osteonics Corp. dba Stryker Orthopaedics

Reference device:

- Mpact 3D Metal - DMLS, K202568, Medacta International SA

IV. Device Description

The GMK 3D Metal Tibial Tray is a line extension to Medacta GMK Total Knee System.

The subject devices are sterile, individually packaged implants designed for cementless or cemented use in Total Knee Arthroplasty procedures.

The GMK 3D Metal Tibial Tray is available in eleven sizes plus two bridge versions with right and left configuration.

The subject devices are manufactured using a Direct Metal Laser Sintering (DMLS) process with titanium alloy powder (Ti-6Al-4V) according to ASTM F2924-14.

V. Indications for Use

The GMK® knee prosthesis is designed for cemented application in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.

The GMK 3D Metal® Tibial Baseplate is indicated for cementless or cemented application if there is evidence of sufficient sound bone to seat and support the components.

This knee replacement system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis
- Collagen disorders, and avascular necrosis of the femoral condyle
- Post traumatic loss of joint configuration
- Primary implantation failure

Tibial wedges cemented are to be attached to the tibial baseplate with both the fixing cylinders and bone cement. The screwed tibial augments are for screwed fixation to the tibial baseplate. In case a semi-constrained liner is used, an extension stem must be implanted both on the tibial and on the femoral components. In case a GMK Revision or GMK Sphere Revision tibial tray is used, an extension stem must be implanted.

It is not possible to implant tibial wedges and extension stems with the GMK 3D Metal® Tibial Baseplate.

Limitations for use for GMK SPHERE/GMK SPHERIKA used with kinematic alignment

GMK® Sphere and GMK® SpheriKA can be implanted in kinematic alignment. In this case, this knee replacement system is indicated for:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis
- Collagen disorders, and/or avascular necrosis of the femoral condyle
- Moderate valgus, varus, or flexion deformities

VI. Comparison of Technological Characteristics

The subject devices are substantially equivalent to the predicate, Triathlon Tritanium Tibia Baseplate (K123486), with regards to the following characteristics:

- Primary stability;
- Materials;
- Biocompatibility;
- Device usage;
- Packaging;
- Shelf-life; and
- Sterilization.

The subject implants differ from the predicate device, Triathlon Tritanium Tibia Baseplate (K123486) as follows:

- Design;
- Sizes;
- Secondary stability.

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

Based on the comparison of technological characteristics and performance data provided within this submission, the data supports the substantial equivalence of the GMK 3D Metal Tibial Tray to the identified predicate devices.

VII. Performance Data

Based on the risk analysis, design validation and performance 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*
  - 3D Metal Tibia Tray - Anthropometric Study
  - Design Validation wetlab

- *PERFORMANCE TESTING*
  - Stereological evaluation according to ASTM F1854-15
  - Tension test on 3D metal honeycomb trabecular structure according to ASTM F1147-05(2017)e1
  - Static shear test on 3D metal honeycomb trabecular structure according to ASTM F1044-05(2017)e1

- Dynamic shear test on 3D metal honeycomb trabecular structure according to ASTM F1160-14(2017)e1
- Taber abrasion resistance test on 3D metal honeycomb trabecular structure according to ASTM F1978-18
- GMK 3D Metal Tibial Tray cementation study
- GMK 3D Metal Tibial Tray Dynamic endurance fatigue test according to ASTM F1800-19e1

- *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.

- *BIOCOMPATIBILITY evaluation*

- *SHELF-LIFE evaluation*

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the GMK 3D Metal Tibial Tray are substantially equivalent to the predicate devices.