February 26, 2026

Medacta International S.A.
% Christopher Lussier
Senior Director, Quality and Regulatory
Medacta USA
6386 Global Drive, Suite 101
Memphis, Tennessee 38141

Re: K253328
Trade/Device Name: GMK 3D Metal Tibial Tray Extension
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Codes: MBH, JWH
Dated: September 29, 2025
Received: January 12, 2026

Dear Christopher 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2026.02.26 12:48:36 -05'00'

For Lixin Liu, Ph.D.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253328

Please provide the device trade name(s).

GMK 3D Metal Tibial Tray Extension

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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 and Regulatory, Medacta USA
Date Prepared: September 29, 2025

II. Device

Device Proprietary Name:	*GMK 3D Metal Tibial Tray Extension*
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 predicate device:

- *GMK 3D Metal Tibial Tray*, K221850, Medacta International SA

IV. Device Description

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

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

Analogously to the predicate devices, 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 and predicate devices (K221850) are substantially equivalent with respect to the following characteristics:

- Sizes;
- Design;
- Primary stability;
- Secondary stability;
- Materials;
- Surface finishing;
- Biocompatibility;
- Device usage;
- Sterility;
- Shelf-life; and
- Packaging.

The subject devices differ from the predicate devices (K221850) with respect to:

- Manufacturing process.

Discussion
The only difference between the subject and predicate devices is the manufacturing process but it does not arise new issues with respect to safety and effectiveness since the mechanical performance is not affected as demonstrated by the performed mechanical tests.
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 Extension to the identified predicate device.

VII. Performance Data

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

Non-Clinical Studies

- *PERFORMANCE TESTING*
  - Tension test according to ASTM F1147-05(2017)e1
  - Static shear test according to ASTM F1044-05(2017)e1
  - Dynamic shear test according to ASTM F1160-14(2017)e1
  - Taber abrasion resistance test according to ASTM F1978-18
  - 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> and USP <161>)
  - 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 subject devices are substantially equivalent to the predicate devices.