September 15, 2026

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

Re: K262057
Trade/Device Name: GMK Extension
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: June 18, 2026
Received: June 18, 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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: 2026.09.15 16:47:12 -04'00'

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.	K262057

Please provide the device trade name(s).

GMK Extension

Please provide your Indications for Use below.

The GMK knee cemented 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 use of the cementless GMK femur is limited to cases in which the surgeon considers the bone quality to be sufficient for cementless applications.

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 augments cemented are to be attached to the tibial baseplate with both the fixing cylinders and bone cement. The screw-fixed 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 augments, offsets, and extension stems with the GMK 3D Metal Tibial Baseplate and Full PE tibial components.

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).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

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: June 17, 2026

II. Device

Device Proprietary Name:	GMK Extension
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 predicate devices.

Primary Predicate device:

- GMK Full PE Tibial Components, K131310, Medacta International SA

Additional Predicate devices:

- GMK Sphere E-CROSS CR Tibial Inserts, GMK Sphere E-CROSS Flex Tibial Inserts and GMK Sphere E-CROSS Resurfacing Patella, K202022, Medacta International SA
- GMK® Total Knee System, K090988, Medacta International SA
- GMK Spherika Femurs and Fixed Tibial Trays Plus, K211004, Medacta International SA
- GMK Short Stem, K133630, Medacta International SA
- GMK Sphere & GMK SpheriKA Cementless, K223548, Medacta International SA

IV. Device Description

The GMK Sphere FULL PE FLEX and FLEX E-CROSS Tibias and the GMK Primary Oblique Extension Stem are a line extension designed to provide a larger product offering in Medacta GMK Primary and Sphere portfolio.

GMK Sphere FULL PE FLEX and FLEX E-CROSS Tibias are sterile, single-use, implantable devices used to replace the tibial plateau of the knee joint. They are intended to be an alternative to the metal-backed system (Metal tibial tray + tibial insert) increasing the thickness of the polyethylene compared with an identically sized metal-backed one.
The fixation with Tibial Bone is achieved by bone cement. Two versions are available: one made from UHMWPE (ISO 5834-2 Type 1) and the other from E-CROSS (Vitamin E Highly Crosslinked UHMWPE).
They are available in 15 different sizes, each characterized by a different thickness.

The GMK Primary Oblique Extension Stem is a sterile, single-use, implantable device designed for use in total knee arthroplasty as part of the GMK Primary Total Knee System.
It is available in a single size and is manufactured from Ti6Al4V in accordance with ISO 5832-3.
It is intended to be assembled exclusively with compatible tibial baseplates of the GMK Primary Total Knee System to provide additional stability to the tibial component.

V. Indications for Use

The GMK knee cemented 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 use of the cementless GMK femur is limited to cases in which the surgeon considers the bone quality to be sufficient for cementless applications.

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 augments cemented are to be attached to the tibial baseplate with both the fixing cylinders and bone cement. The screw-fixed 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 augments, offsets, and extension stems with the GMK 3D Metal Tibial Baseplate and Full PE tibial components.

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

GMK Sphere FULL PE FLEX and FLEX E-CROSS Tibias
The subject GMK Sphere FULL PE FLEX and FLEX E-CROSS Tibias and predicate devices (K131310, K202022, K090988 and K211004) are substantially equivalent with respect to the following characteristics:

- Design
- Articular Surface
- Size
- Configuration
- Thickness
- Material
- Radiopaque markers
- Cement pockets
- Keel design
- Fixation
- Biocompatibility
- Device usage
- Packaging
- Shelf-life
- Sterilization

GMK Primary Oblique Extension Stem
The subject GMK Primary Oblique Extension Stem and predicate device (K133630) are substantially equivalent with respect to the following characteristics:

- Diameter
- Length
- Modular connection
- Material
- Fixation
- Biocompatibility
- Device usage
- Packaging
- Shelf-life
- Sterilization

The only difference between the subject GMK Primary Oblique Extension Stem and predicate device (K133630) is the design of the stem.

Discussion
The partially different design of the stem has not any impact on the subject devices' safety and effectiveness as it does not introduce new or more critical loading conditions when compared to the predicate device (K133630).

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:

DESIGN VALIDATION

- Comparative dimensional evaluation between the subject GMK Sphere Full PE and the predicate devices (K131310, K202022, K090988 and K211004)
- Anthropometric Study GMK Primary Oblique Extension Stem Design Optimization to ensure Patient Coverage

PERFORMANCE TESTING

- Comparative analysis of the GMK Sphere Full PE Flex versus the metal-backed solution (GMK Tibial Tray + Flex ECross tibial insert) with regard to potential risks and performance aspects, including excessive debris generation due to wear, rotational instability of the tibial component, anterior/posterior and medio/lateral femoral luxation, and range of motion (ROM) limitations.
- GMK Sphere Full PE static endurance test against antero/posterior loads.
- Comparative evaluation of the GMK Primary Oblique Extension Stem with the predicate device (K133630) focusing on design features and dimensions relevant to clinical use and mechanical performance.

PYROGENICITY

- Bacterial endotoxin test (LAL test) according to European Pharmacopoeia §2.6.14 (which is harmonized with 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.

BIOCOMPATIBILITY assessment

*SHELF-LIFE evaluati*on

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.