September 18, 2020

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

Re: K202022
Trade/Device Name: GMK-SPHERE Tibial inserts FLEX Tibial Insert CR and Resurfacing Patella made of E-CROSS (Vitamin E Highly Crosslinked UHMWPE)
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 21, 2020
Received: July 22, 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,

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K202022

Device Name
GMK-SPHERE Tibial inserts FLEX Tibial Insert CR and Resurfacing Patella made of E-CROSS (Vitamin E Highly Crosslinked UHMWPE)

Indications for Use *(Describe)*
GMK knee prosthesis is designed for cemented use in total knee arthroplasty, 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.
• Avascular necrosis of femoral condyle.
• Post traumatic loss of joint configuration.
• Primary implantation failure.

GMK Sphere can be implanted using a kinematic alignment approach. When a kinematic alignment approach is utilized, 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/or avascular necrosis of the femoral condyle.
• Moderate valgus, varus, or flexion deformities.

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 tibial tray is used, an extension stem must be implanted.

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 and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Director of Quality and Regulatory, Medacta USA
Date Prepared: July 20, 2020

## II. Device

| | |
|---|---|
| Device Proprietary Name: | GMK-SPHERE Tibial inserts FLEX Tibial Insert CR and Resurfacing Patella made of E-CROSS (Vitamin E Highly Crosslinked UHMWPE) |
| Common or Usual Name: | Tibial Inserts and Resurfacing Patella |
| Classification Name: | Knee joint patellofemorotibial polymer/metal/polymer semiconstrained 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:

- Medacta International SA, GMK Sphere K121416
- Medacta International SA, GMK Sphere Extension, K140826
- Medacta International SA, GMK Knee Prosthesis- GMK Sphere Tibial Insert Flex, K162035
- Medacta International SA, GMK Sphere CR Tibial Inserts, K181635
- Medacta International SA, GMK Total Knee System, K090988
- Medacta International SA, GMK Resurfacing Patella Size 4, K113571

Reference predicate:

- Zimmer-Biomet, Vivacit-E Vitamin E Highly Crosslinked Polyethylene Liners, K120370

## IV. Device Description

The GMK Sphere Flex insert E-CROSS (Vitamin E Highly Crosslinked UHMWPE) , GMK Sphere CR E-CROSS (Vitamin E Highly Crosslinked UHMWPE) inserts and the Resurfacing Patella (Vitamin E Highly Crosslinked UHMWPE) are a line extension to the GMK Sphere Total Knee System and are:

- Tibial insert Fixed Sphere FLEX: Left and Right, Sizes 1-6, Thicknesses 10-11-12-13-14-17-20 mm, E-cross-Vitamin-E Highly Crosslinked UHMWPE;
- Tibial Insert Fixed SPHERE CR: Left and Right, Sizes 1-6, Thicknesses 10-11-12-13-14mm, E-cross-Vitamin-E Highly Crosslinked UHMWPE;
- Patella resurfacing E-Cross: Sizes 1-4 E-Cross - Vitamin-E Highly Crosslinked UHMWPE

GMK Sphere implants are sterile implantable devices designed for tricompartmental replacement of the natural knee joint.

They are a line extension to Medacta previously cleared implants: GMK Sphere (K121416), GMK Sphere Extension, (K140826), GMK Knee Prosthesis- GMK Sphere Tibial Insert Flex (K162035), GMK Sphere CR Tibial Inserts (K181635) and GMK Total Knee System (K0909889) and GMK Resurfacing Patella Size 4 (K113571).

Liners and Resurfacing patella subject of this submission are implants made of E-Cross (Vitamin-E Highly Crosslinked UHMWPE).

The introduction of the subject items do not require additional instrumentation needed during the surgical procedure and do not alter the indented use or outcomes.

The following components of the GMK Sphere have been cleared previously under K121416 and K140826 predicate device:

- Femoral Component Left and Right, Sizes 1-7 Co-Cr-Mo (ISO 5832-4 Third Edition 2014-09-15 Implants for Surgery – Metallic Materials – Part 4: Cobalt-Chromium-Molybdenum Casting Alloy);
- Femoral Component Left and Right, Sizes 1+ to 6+ (intermediate sizes) Co-Cr-Mo (ISO 5832-4 Third Edition 2014-09-15 Implants for Surgery – Metallic Materials – Part 4: Cobalt-Chromium-Molybdenum Casting Alloy);
- Tibial tray fixed cemented Left and Right, 4 intermediate sizes Co-Cr-Mo (ISO 5832-4 Third Edition 2014-09-15 Implants for Surgery – Metallic Materials – Part 4: Cobalt-Chromium-Molybdenum Casting Alloy);
- Tibial Insert Fixed Flex, Left and Right, Sizes 1-6, 10mm -20mm UHMWPE (ISO 5834 2:2011 Implants for Surgery – Ultra-High-Molecular-Weight Polyethylene – Part 2: Moulded Forms) Type 1, Ti6Al5V (ISO 5832-3:1996 Implants for Surgery – Metallic Materials – Part 3: Wrought Titanium 6-Aluminium 4-Vanadium Alloy);
- Tibial Insert Fixed Flex, Left and Right, Sizes 1-6, 11mm and 13mm UHMWPE (ISO 5834-2:2011 Implants for Surgery – Ultra-High-Molecular-Weight Polyethylene – Part 2: Moulded Forms) Type 1, Ti6Al4V (ISO 5832-3:1996 Implants for Surgery – Metallic Materials – Part 3: Wrought Titanium 6-Aluminium 4-Vanadium Alloy; and
- Instrumentation.

The following components of the GMK Sphere have been cleared previously under the Medacta GMK Total Knee System:

- Resurfacing patella Sizes 1-4 (K090988 and K113571);
- Tibial tray fixed cemented Left and Right, Sizes 1-6 (K090988); and
- Primary extension stem Ø 11mm/ L 65mm (K090988) and L 30mm (K133630).

In detail, the liners and the resurfacing patella subject of the current submission are compatible with the all the GMK Sphere tibial baseplates and femurs previously cleared.

## V. Indications for Use

GMK knee prosthesis is designed for cemented use in total knee arthroplasty, 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.
• Avascular necrosis of femoral condyle.
• Post traumatic loss of joint configuration.
• Primary implantation failure.

GMK Sphere can be implanted using a kinematic alignment approach. When a kinematic alignment approach is utilized, 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/or avascular necrosis of the femoral condyle.
• Moderate valgus, varus, or flexion deformities.

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 tibial tray is used, an extension stem must be implanted.

## VI. Comparison of Technological Characteristics

- *Tibial insert*

- Tibial insert Fixed Sphere FLEX E-CROSS (Vitamin E Highly Crosslinked UHMWPE) implants and the Medacta predicate devices GMK SPHERE (K121416, K140826, K162035 and K181635) share the following characteristics:

  - Indications for Use;
  - Sizes;
  - Packaging,
  - Device Usage;
  - Biocompatibility
  - Shelf Life; and
  - Sterilization Method.

  Tibial insert Fixed Sphere FLEX E-CROSS (Vitamin E Highly Crosslinked UHMWPE) implants are technologically different from the predicate device as follows:

  - Materials
  - Design

- Tibial Insert Fixed SPHERE CR E-CROSS (Vitamin E Highly Crosslinked UHMWPE) implants and the predicate devices GMK SPHERE (K121416, K140826, K162035 and K181635) share the following characteristics:

  - Indications for Use;
  - Sizes;
  - Packaging
  - Device Usage;
  - Biocompatibility;

- Shelf Life; and
- Sterilization Method.

Tibial insert Fixed SPHERE CR E-CROSS (Vitamin E Highly Crosslinked UHMWPE)implants are technologically different from the predicate device as follows:

- Materials

- Patella Resurfacing E-CROSS (Vitamin E Highly Crosslinked UHMWPE) implants and the predicate devices GMK SPHERE (K090988, K113571, K121416, K140826, K162035 and K181635) share the following characteristics:
  - Design;
  - Sizes;
  - Device usage;
  - Biocompatibility;
  - Sterility;
  - Shelf life;
  - Packaging;

Patella Resurfacing E-CROSS (Vitamin E Highly Crosslinked UHMWPE)implants are technologically different from the predicate device as follows:

- Materials

## VII. Performance Data

A review of the mechanical data on the subject and predicate devices indicates that the subject devices are equivalent to devices currently cleared for use and do not alter the intended surgical outcomes. The purpose of this submission is to introduce new GMK Sphere inserts and Resurfacing patella made of Vitamin E Highly Crosslinked UHMWPE. The introduction of the subject items do not require additional instrumentation needed during the surgical procedure. The new inserts and resurfacing patella design introduction was evaluated by risk analysis to identify any new risks associated. Based on the risk analysis, additional tests have been performed in order to demonstrate that the new E-Cross inserts and new E-Cross Resurfacing patella are as safe as effective as the predicate devices.

Testing was conducted according to written protocols with acceptance criteria that were based on standards. The following mechanical studies were performed in support of a substantial equivalence determination:

Non-Clinical Studies:

- PERFORMANCE TESTING

  - "GMK® SPHERE TIBIAL INSERTS MADE OF E-CROSS (VITAMIN E HIGHLY CROSSLINKED UHMWPE): CONSTRAINT A/P DRAW TEST - M/L SHEAR TEST - ROTARY LAXITY TEST, Test Report A.1
  - GMK®-SPHERE TIBIAL INSERTS E-CROSS (VITAMIN E HIGHLY CROSSLINKED UHMWPE): WEAR TEST IN KNEE SIMULATOR MACHINE WITH LOAD CONTROL, test Report A.2
  - GMK® SPHERE TIBIAL INSERT FLEX MADE OF E-CROSS (VITAMIN EHIGHLY CROSSLINKED UHMWPE): MAXIMUM POSTERO-ANTERIOR LOAD THAT CAN OCCUR ON THE TIBIAL INSERT DURING ACTIVITIES OF DAILY LIVING, Test Report A.3
  - GMK® SPHERE TIBIAL INSERT FLEX MADE OF E-CROSS (VITAMIN EHIGHLY CROSSLINKED UHMWPE): DYNAMIC ENDURANCE TEST UNDER PA LOAD, Test Report A.4
  - GMK-SPHERE RESURFACING PATELLA MADE OF E-CROSS (VITAMIN E HIGHLY CROSSLINKED UHMWPE): CONTACT PRESSURE AND AREAS, Test Report A.5
  - GMK®-SPHERE E-CROSS TIBIAL INSERTS CONTACT PRESSURE AND AREAS: COMPARATIVE ANALYSIS BETWEEN E-CROSS and UHMWPE DEVICES, Test Report A.6
  - MATERIAL CHARACTERIZATION OF MEDACTA'S VITAMIN E HIGHLY CROSSLINKED UHMWPE (E-CROSS)

- PYROGENICITY

  - Bacterial Endotoxin Test (LAL test) was conducted 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

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## VIII. Conclusion

Based on the above information, the GMK Sphere Flex insert E-CROSS (Vitamin E Highly Crosslinked UHMWPE), GMK Sphere CR E-CROSS (Vitamin E Highly Crosslinked UHMWPE) inserts and the E-CROSS Resurfacing Patella (Vitamin E Highly Crosslinked UHMWPE) are substantially equivalent to the identified predicate devices.

Substantial equivalence has been demonstrated through a comparison of intended use, design, and technological characteristics, as well as performance evaluations.

The GMK Sphere Extension implants are as safe and effective as the predicate devices

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