November 16, 2021

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

Re: K213071
Trade/Device Name: MOTO™ Partial Knee & MOTO PFJ Systems Extension
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX, KRR, JWH, NPJ
Dated: November 11, 2021
Received: November 12, 2021

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, 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)*

K213071

Device Name
MOTO™ Partial Knee & MOTO PFJ Systems Extension

Indications for Use *(Describe)*

o MOTO™ Partial Knee System
The MOTO™ Partial Knee System is designed for cemented use in partial knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components. Partial replacement of the articulating surfaces of the knee is indicated when only one compartment of the joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

o MOTO™ PFJ System
The MOTO™ PFJ is designed for cemented use in partial knee arthroplasty, if there is evidence of enough sound bone to seat and support the components. Patellofemoral replacement is indicated in the following cases:
• Osteoarthritis, post-traumatic arthritis, polyarthritis, severe chondrocalcinosis of the patellofemoral joint.
• Previously failed surgical attempts (i.e. arthroscopy, lateral release, tibial tubercle elevation, cartilage transplantation).
• History of patellar dislocation or fracture, resulting in cartilage degeneration of the patellofemoral joint.
• Degeneration induced by dysplasia.

If the surgeon evaluates an unequivocal indication for replacement of the patellofemoral joint, with or without a patella resurfacing, which outweighs the risks associated with the surgery, PFJ replacement may be considered, particularly for young patients.

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.

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510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director of Quality and Regulatory, Medacta USA
Date Prepared: September 22, 2021
Date Revised: November 12, 2021

II. Device

Device Proprietary Name:	MOTO™ Partial Knee & MOTO PFJ Systems Extension
Common or Usual Name:	Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal/Polymer
Classification Name:	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Primary Product Code	HSX
Secondary Product Code:	KRR, JWH, NPJ
Regulation Number:	21 CFR 888.3520, 21 CFR 888.3540 and 21 CFR 888.3560
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:
Primary predicate device

- MOTO™ Partial Knee System, K162084, Medacta International SA

Additional predicate devices

- MOTO™ Lateral Partial Knee System, K183029, Medacta International SA
- MOTO™ PFJ System, K200122, Medacta International SA

Additional reference devices

- GMK Sphere E-cross, K202022, Medacta International SA
- GMK Total Knee System – TiNbN Coating, K202684, Medacta International SA

IV. Device Description

The purpose of this submission is to gain clearance for the MOTO™ Partial Knee & MOTO™ PFJ Systems Extension and to extend the compatibility of the already cleared MOTO Patella. Specifically, both the new MOTO Patella and the already cleared one (K200122) may be used in the following combinations:

- with the MOTO PFJ
- with the MOTO PFJ and with the MOTO Partial Knee System (K162084, K183029), GMK UNI (K162084),
- alone (without MOTO PFJ) with the GMK Primary or GMK Sphere devices (K090988, K120790, K121416, K122232, K140826, K142069 and K202684) or GMK Spherika (K211004).

The MOTO™ Partial Knee & MOTO™ PFJ Systems is a line extension to provide a larger product offering. The subject devices are sterile implantable devices designed for cemented use in partial knee arthroplasty procedures. The MOTO™ Partial Knee & MOTO™ PFJ Systems extension includes:

- Medial femoral components TiNbN coated, left medial and right medial, sizes from 1 to 10;
- Lateral femoral components TiNbN coated, sizes from 1 to 7;
- Medial tibial inserts fixed E-cross, left medial and right medial, sizes from 1 to 8 and 6 thicknesses from 8 to 14;
- Lateral tibial inserts fixed E-cross, sizes from 1 to 8 and 6 thicknesses from 8 to 14;
- Patello Femoral Joint TiNbN coated, left and right, sizes from 1 to 6;
- MOTO Patella E-cross, 6 sizes.

The subject femoral components, as well as the patello femoral joint, are manufactured from cobalt-chromium-molybdenum alloy (Co-Cr-Mo) according to ISO 5832-4 with Titanium Niobium Nitride (TiNbN) coating.
The subject tibial inserts, as well as the MOTO patella, are made of E-Cross (Vitamin-E Highly Crosslinked UHMWPE).

V. Indications for Use

o MOTO™ Partial Knee System

The MOTO™ Partial Knee System is designed for cemented use in partial knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components. Partial replacement of the articulating surfaces of the knee is indicated when only one compartment of the joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

o MOTO™ PFJ System

The MOTO™ PFJ is designed for cemented use in partial knee arthroplasty, if there is evidence of enough sound bone to seat and support the components. Patellofemoral replacement is indicated in the following cases:

- Osteoarthritis, post-traumatic arthritis, polyarthritis, severe chondrocalcinosis of the patellofemoral joint.
- Previously failed surgical attempts (i.e. arthroscopy, lateral release, tibial tubercle elevation, cartilage transplantation).
- History of patellar dislocation or fracture, resulting in cartilage degeneration of the patellofemoral joint.
- Degeneration induced by dysplasia.

If the surgeon evaluates an unequivocal indication for replacement of the patellofemoral joint, with or without a patella resurfacing, which outweighs the risks associated with the surgery, PFJ replacement may be considered, particularly for young patients.

VI. Comparison of Technological Characteristics

The MOTO™ Partial Knee & MOTO™ PFJ Systems Extension implants and the predicate devices (K162084, K183029 and K200122) share the following characteristics:

- indications for use;
- sizes;
- shape and design;
- fixation and stability;
- biocompatibility;
- device usage;
- sterility;
- shelf-life; and
- packaging.

The MOTO™ Partial Knee & MOTO™ PFJ Systems Extension implants differ from the predicate devices (K162084, K183029 and K200122) as follow:

- MOTO tibial inserts and MOTO Patella material; and
- femoral components and MOTO PFJ coating.

Discussion

Medacta International SA has not made any change to the indications for use, sizes, general design and shape, fixation and stability features, 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 MOTO™ Partial Knee & MOTO™ PFJ Systems Extension implants to the identified predicate devices.

VII. Performance Data

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

Non-Clinical Studies

- *PERFORMANCE TESTING*
  - TiNbN coated MOTO Femoral component - Mechanical performances
  - TiNbN coated MOTO Femoral component – Wear behavior
  - TiNbN coating Excessive Ions release
  - TiNbN coated PFJ implant - Mechanical performances
  - TiNbN coated PFJ implant – Wear behavior
  - E-Cross MOTO medial and lateral tibial inserts – Wear behavior, ROM and constraints rationale
  - MOTO Partial knee system – E-Cross medial and lateral tibial inserts: static ML SHEAR and AP draw test of the insert-tray clipping system according to ASTM F2083
  - MOTO E-Cross tibial inserts - Contact pressures and areas according to ASTM F2083
  - Contact pressure and areas: MOTO Patella articulating on GMK-Sphere & GMK-Primary femoral component
  - Constraint comparison within Medacta MOTO Patella & Medacta EVOLIS Patella in terms of jump height
  - E-Cross MOTO Patella – Wear behavior, ROM and constraints rationale
  - Constraints equivalence of GMK Resurfacing and MOTO Patella articulating with GMK Spherika femoral component and GMK Spherika anatomical femoral component and the predicated device
  - Contact areas equivalence of GMK Resurfacing and MOTO Patella articulating with GMK Spherika femoral component and GMK Spherika anatomical femoral component and the predicated device

- *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.

- *BIOCOMBATIBILITY evaluation*

- *SHELF-LIFE evaluation*

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the MOTO™ Partial Knee & MOTO™ PFJ Systems Extension implants are substantially equivalent to the predicate devices.