July 24, 2025

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

Re: K251618
Trade/Device Name: MOTO Partial Knee System 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
Dated: May 27, 2025
Received: May 27, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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: 2025.07.24 15:41:29 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251618

Device Name
MOTO Partial Knee System Extension

Indications for Use *(Describe)*
MOTO Medial, MOTO Lateral and MOTO Sphere 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.

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.

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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: May 27, 2025
Date Revised: July 23, 2025

II. Device

Device Proprietary Name:	MOTO Partial Knee System Extension
Common or Usual Name:	Unicompartmental Knee Prosthesis
Classification Name:	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Primary Product Code	HSX
Regulation Number:	21 CFR 888.3520
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following predicate devices.

Primary Predicate device:

- MOTO Partial Knee & MOTO PFJ Systems Extension, K213071, Medacta International SA

Additional Predicate devices:

- Oxford® Fixed Lateral Bearing Partial Knee Replacement, K133940, Biomet UK, Ltd
- MOTO Partial Knee System, K162084, Medacta International SA
- MOTO Lateral Partial Knee System, K183029, Medacta International SA

Reference device:

- GMK Total Knee System - TiNbN Coating, K202684, Medacta International SA

IV. Device Description

The MOTO Partial Knee System Extension is a Medacta partial knee prosthesis portfolio extension including implantable devices, provided individually packed, sterile and single-use. Specifically, the purpose of this submission is to gain the clearance for:

- MOTO Sphere femoral components, made of Co-Cr-Mo according to ISO 5832-4 and available in 5 sizes with or without TiNbN coating. They are intended to replace the medial or lateral femoral compartment of the natural knee joint and must be implanted in combination with the tibial component of MOTO Medial or MOTO Lateral (K162084, K183029 and K213071);
- 7mm thick MOTO Medial and MOTO Lateral inserts fixed made of E-cross, available in 8 sizes and intended to be coupled with the subject MOTO Sphere femoral components as well as MOTO Medial or MOTO Lateral tibial components (K162084, K183029 and K213071).

V. Indications for Use

MOTO Medial, MOTO Lateral and MOTO Sphere 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.

VI. Comparison of Technological Characteristics

- *MOTO Sphere femoral components*

The subject MOTO Sphere femoral components and the predicate Oxford® Fixed Lateral Bearing Partial Knee Replacement (K133940) are substantially equivalent with respect to the following characteristics:

- Sizes;
- Configuration;
- Design;
- Femoral curvature;
- Fixation;
- Material;
- Biocompatibility;
- Device usage;
- Packaging;
- Shelf-life; and
- Sterilization.

The subject MOTO Sphere femoral components differ from the predicate Oxford® Fixed Lateral Bearing Partial Knee Replacement (K133940) with respect to:

- Coverage; and
- Coating.

- *E-cross MOTO Medial and MOTO Lateral inserts fixed*

The subject 7mm thick E-cross MOTO Medial and MOTO Lateral inserts fixed and the predicate devices (K213071) are substantially equivalent with respect to the following characteristics:

- Sizes;
- Fixation to the baseplate;
- Material;
- Biocompatibility;
- Device usage;
- Packaging;

- Shelf-life; and
- Sterilization.

The only difference between the subject 7mm thick E-cross MOTO Medial and MOTO Lateral inserts fixed and the predicate devices (K213071) is the thickness.

Discussion
The coverage of the subject MOTO Sphere is substantially equivalent to the one of the Oxford® Fixed Lateral Bearing Partial Knee Replacement (K133940). The AP and PD dimensions of the subject devices have been designed slightly increased in larger sizes with respect to the ones of the predicate devices (K133940) in order to increase the range of motion thus this difference does not affect safety and effectiveness.
MOTO Sphere TiNbN coated version does not raise any different questions of safety and effectiveness since it is the same coating as Medacta predicate devices (K213071).
The new thickness of the subject devices has been designed to cover a larger intended population with respect to the predicate devices (K213071), but it does not introduce different questions of safety and effectiveness as demonstrated by performance testing.

The comparison of technological characteristics and performance data provided within the submission supports the substantial equivalence of the subject devices respect to the predicate devices.

VII. Performance Data

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

Non-Clinical Studies

- *PERFORMANCE TESTING*
  - Fatigue endurance test of the posterior condyle
  - Contact pressures and areas according to ISO 21536
  - Comparative dimensional evaluation of the MOTO Sphere femoral component
  - MOTO Sphere femoral component - Cementation area
  - MOTO Sphere femoral component - Range of Motion according to ISO 21536 and ASTM F2083-21
  - TiNbN coated MOTO femoral components - Wear behaviour
  - MOTO Partial knee system medial and lateral tibial insert made of UHMWPE + Vitamin E crosslinked: wear test in knee simulator machine with load control according to ISO 14243-1 and ISO 14243-2
  - Thickness 7mm E-Cross MOTO Tibial Inserts - Comparison to the MOTO range of products

- *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* assessment

- *SHELF-LIFE* evaluation

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.