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

January 30, 2019

Re: K183029
Trade/Device Name: MOTO™ Lateral Partial Knee System
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: October 24, 2018
Received: November 1, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel S. Ramsey -S
2019.01.30 15:53:50 -05'00'

FOR Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K183029

Device Name
MOTO Lateral Partial Knee System

Indications for Use *(Describe)*

The MOTO™ Lateral 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 side of the joint is affected due to the compartmental primary degenerative or posttraumatic 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.

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510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager, Medacta International SA
Date Prepared: October 24, 2018

II. Device

Device Proprietary Name:	MOTO™ Lateral Partial Knee System
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 devices:

- JOURNEY Unicondylar Femoral Implant - K073175, Smith & Nephew INC.;
- JOURNEY Unicondylar Tibial Baseplates - K102069, Smith & Nephew INC.;
- ZIMMER Unicompartimental Knee System - K033363, Zimmer, INC.; and
- MOTO™ Partial Knee System - K162084, Medacta International SA.

IV. Device Description

The MOTO™ Lateral 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 side of the joint is affected due to the compartmental primary degenerative or posttraumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

MOTO™ Lateral Partial Knee System design is characterized by:
- a femoral component designed to anatomically fit the lateral femoral condyle
- a tibia component, designed to anatomically fit the lateral tibial condyle
- a fixed tibia insert, with a flat articulating surface with rounded border

MOTO™ Lateral Partial Knee System has been designed in cemented version only.
The femoral component is made of cobalt-chromium-molybdenum (Co-Cr-Mo per ISO 5832-4), and the tibial component consists of an ultra-high molecular weight polyethylene (UHMWPE per ISO 5834-2 Type 1) insert, and a metal baseplate component (Ti-6Al-4V per ISO 5832-3).
The MOTO™ Lateral Partial Knee System implants are offered sterile (via gamma irradiation for the femoral and tibial tray components and ethylene oxide for the tibial insert components), are intended for single use only, and may not be re-sterilized

The Lateral Femoral Component (cemented) is symmetrically shaped (suitable for both left and right side) and designed with two (2) fixation pegs for all the sizes. It is available in seven (7) sizes (1 - 7).

The Lateral Fixed Tibial Insert has a fixed design, is symmetrically shaped (suitable for both left and right side) and is available in eight (8) sizes (1 – 8). Each size is offered in six (6) levels of thickness (8, 9, 10, 11, 12, 14 mm). It is fixed through a snapping mechanism with baseplate.

The Lateral Fixed Tibial Tray (cemented) has a fixed bearing design with one (1) triangular keel and two (2) 'mushroom' shaped pegs to ensure primary stability. Available in eight (8) sizes (1 – 8), the Lateral Fixed Tibial Tray is offered in both Right Lateral (RL) and Left Lateral (LL) options for each size.

V. Indications for Use

The MOTO™ Lateral 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 side of the joint is affected due to the compartmental primary degenerative or posttraumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

Discussion:

The Indications for Use Statement is identical to the predicate device MOTO™ Partial Knee System (K162084). It is also similar to the other predicate devices IFU: the only difference is that the subject device calls out the requirements for "evidence of sufficient sound bone to seat and support the components", and the predicate device cites specific example of degenerative joint disease ("osteoarthritis, traumatic arthritis, or avascular necrosis"). These differences do not create new intended uses for the subject device; the subject and predicate devices are all prostheses intended for use in knee arthroplasty.

VI. Comparison of Technological Characteristics

The design features, and materials of the subject devices are substantially equivalent to those of the predicate devices. The tables below compare characteristics of the subject and predicate devices.

Feature	MOTO™ Lateral Partial Knee System - Anatomical Femoral Component	MOTO™ Partial Knee System - Anatomic Femoral Component (K162084)	Smith & Nephew Journey (K073175)	Zimmer UNI (K033363)
Sizes	7 sizes (Size 1 -7)	10 sizes (Size 1-10)	Same	7 sizes (Size A – G)
Configuration	LLRL	RM and LM	RM/LL and LM/RL	RM/LL and LM/RL
Material	CoCrMo – ISO 5832-4	Same	Same (with an oxinium oxidized zirconium coating)	Same
Cemented?	Cemented	Same	Same	Same
Device Usage	Single Use	Same	Same	Same
Sterility	Provided sterile via Gamma Radiation	Same	Same	Same
Shelf Life	5 Years	Same	Same	> 5 Years
Stabilization pegs	2 Pegs	2 pegs for sizes 1-7 and 3 pegs for sizes 8-10	Same	Same

Feature	MOTO™ Lateral Partial Knee System - Fixed Tibial Insert	MOTO™ Partial Knee System - Fixed Tibial Insert (K162084)	Zimmer UNI (K033363)
Sizes	8 sizes (from 1 to 8)	Same	6 sizes (from 1 to 6)
Thickness	Each size is offered in 6 levels of thickness (8, 9, 10, 11, 12, 14 mm)	Same	Same
Material	UHMWPE (ISO 5834 -2) Type 1	Same	Same
Device Usage	Single Use	Same	Same
Sterility	Provided sterile via Ethylene Oxide	Same	Same
Shelf Life	5 years	Same	> 5 years

Feature	MOTO™ Lateral Partial Knee System - Fixed Tibial Tray	MOTO™ Partial Knee System – Fixed Plus Tibial Tray (K162084)	Smith & Nephew Journey (K102069)	Zimmer UNI (K033363)
Sizes	8 sizes (from 1 to 8)	Same	6 sizes	6 sizes (from 1 to 6)
Configurations	RL and LL	RM and LM	RM/LL and LM/RL	RM and LM
Material	Ti-6Al-4V (ISO 5832-3)	Same	Same	Ti-6Al-4V with PMMA precoat
Cemented?	Cemented	Same	Same	Same
Device Usage	Single Use	Same	Same	Same
Sterility	Provided sterile via Gamma Radiation	Same	Unknown	Same
Shelf Life	5 years	Same	Unknown	> 5 years
Stabilization	Stabilized with 1 keel and 2 pegs	Same	Same	Same
Fixed Bearing?	Fixed bearing	Same	Same	Same

The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the subject devices is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Due to the extensive history of use in currently marketed medical devices, biocompatibility testing conducted on the predicate device [MOTO™ Partial Knee System (K162084)] for the same materials supports the biological safety of the MOTO™ Lateral Partial Knee System.

VII. Performance Data

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:
  DESIGN VALIDATION
- Validation Cadaveric Workshop *according to Instrument evaluation form dated 16-Dec-16*
- Design Validation Report

CHARACTERIZATION TESTING

- Fatigue Endurance Test of the Posterior Condyle *according to Medacta Test Protocol IL 07.09.455/Rev.0, Dated 09.Feb.2018 and EndoLab test Report 167.180320.20.838 rev.0, dated 03.May.2018.* Test Report A1, rev.0
- Comparative Coverage Test of the Moto Lateral Femoral Component. Test Report A2, rev.0
- Rationale to Demonstrate Lateral Tibial Tray Conservative Design in Comparison with the Medial Tibial Tray in Terms of Mechanical Resistance *according to ASTM F1800:12 and ASTM F1814-97a.* Test Report B1, rev.0.
- Comparative Coverage Test of the Moto Lateral Tibia Tray. *Test Report B2, rev.0.*
- Rationale to Demonstrate Moto Lateral Conservative Design in Terms of Contact Area and Pressure in Comparison with the Medial Implant *according to Test Reports C1_rev.0, C2_rev.0, C4_rev.0 already provided in the Original Submission* MOTO™ Partial Knee System (K162084) *and the Test Report D7_rev.0 already provided as per Additional Information request of that same submission.*Rationale C1, rev 0.
- Static ML/LM Shear and AP/PA Draw Test of the Insert-Tray Clipping System *according to Guidance Document for Testing Non-Articulating, Mechanically Locked, Modular Implant Components; Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/ Polymer Porous-Coated Uncemented Prosthesis, Guidance for Industry and FDA; ASTM F2083:12; ASTM F1223:08; ASTM 1814:15*. Test Report C2 rev.0.
- Lateral Femoral Component – Fixed Tibia Insert, Range of Motion, according to Standard ISO 21536 and ASTM 2083. Test Report C3, rev.0.

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.

➢ Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion:

Based on the above information, the MOTO™ Lateral Partial Knee System can be considered 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 MOTO™ Lateral Partial Knee System implants are as safe and effective as the predicate devices JOURNEY Unicondylar Femoral Implant (K073175); JOURNEY Unicondylar Tibial Baseplates (K102069); ZIMMER Unicompartimental Knee System (K033363) and MOTO Partial Knee System (K162084).