April 20, 2020

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

Re: K200122
Trade/Device Name: MOTO PFJ System
Regulation Number: 21 CFR 888.3540
Regulation Name: Knee Joint Patellofemoral Polymer/Metal Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRR, JWH, NPJ
Dated: January 17, 2020
Received: January 21, 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,

Ting Song, Ph.D., R.A.C.
Acting 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)*

K200122

Device Name
MOTO PFJ System

Indications for Use *(Describe)*

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.

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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, Director of Quality and Regulatory, Medacta USA
Date Prepared: January 17, 2020

II. Device

Device Proprietary Name:	MOTO PFJ System
Common or Usual Name:	Total Knee Prosthesis
Classification Name:	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
Primary Product Code:	KRR
Secondary Product Codes	JWH, NPJ
Regulation Number:	21 CFR 888.3540 and 21 CFR 888.3560
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- Patellofemoral joint prosthesis, K070695, Zimmer
- NexGen Prolong All-poly patella, K072281, Zimmer

In addition, the following Reference device is cited within the submission:

- GMK (K090988), Medacta International SA

IV. Device Description

The MOTO PFJ System, subject of this submission, consists of:

- Patello Femoral Joint, made of Cobalt-Chromium-Molybdenum alloy
- MOTO Patella, made of UHMWPE

The MOTO PFJ System is intended for replacement of the femoral trochlea of the patellafemoral joint affected by injury and/or disease process.
The MOTO PFJ System is intended for cemented use only.
The MOTO PFJ System may be used alone or in combination with the MOTO Partial Knee System Unicompartmental Prosthesis (Medial K161741 and Lateral K183029) and GMK UNI Prosthesis (K162084), to treat multiple conditions of patellofemoral and tibiofemoral regions of the natural knee. The Patello Femoral Joint component is designed to articulate with natural patella or with the dedicated MOTO Patella.

V. Indications for Use

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

o *Patello Femoral Joint*

The subject Patello Femoral Joint and the predicate Patellofemoral joint prosthesis share the following characteristics:

- indication for use;
- shape;
- fixation and stability features;
- material;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The only difference between the subject Patello Femoral Joint and the predicate device concerns the sizes.

o *MOTO Patella*

The subject MOTO Patella and the predicate NexGen Prolong All-poly patella share the following characteristics:

- indication for use;
- sizes;
- shape;
- fixation and stability features;
- material;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

There are no differences between the subject MOTO Patella and the predicate device.

Discussion

Medacta International SA has not made any change to the intended use, shape, device usage, materials, biocompatibility, sterility, shelf life, and packaging of the subject devices respect to the predicate devices.

The range of product of the Patello Femoral Joint was divided in 6 sizes, with respect to the 5 sizes of the predicate device, in order to cover all the antero-posterior (AP) and medio/lateral (ML) dimensions identified on the basis of a comparative analysis of all PFJ implants currently on the market.

The comparison of technological characteristics and performance data provided within this submission, shows that there are no new risks associated with the subject devices design, and supports the substantial equivalence of the MOTO PFJ System implants to the identified predicate devices.

VII. Performance Data

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

Non-Clinical Studies

- *DESIGN VALIDATION*
    - Shape and Dimension Validation of the MOTO PFJ Femoral Component - *Test Report A1.*
    - MOTO PFJ system Validation cadaveric workshop - *Test Report A2.*

- *CHARACTERIZATION TESTING*

  - Fatigue Endurance Test of the MOTO PFJ Femoral Component – Walking Scenario according to Test Reports 00812-009638-1 and 00812-009638-2 and Test Protocols IL 07.09.459 and IL 07.09.465. *Test report A3*
  - Fatigue Endurance Test of the MOTO PFJ Femoral Component – Squatting Scenario according to Test Reports 00812-007625-3 and 00812-007625-4 and Test Protocols IL 07.09.479 and IL 07.09.480. *Test report A4*
  - Articular Surface Fully Congruent within MOTO PFJ & MOTO. *Test report B1*
  - MOTO PFJ & MOTO Patella Range of Motion. *Test report B2*
  - Comparison within Medacta MOTO Patella and Zimmer NexGen Patella Constraints according to Test Reports 00812-009640-1 and 00812-009640-2 and Medacta Test protocols IL 07.09.552 and IL 07.09.555. *Test report B3*
  - Comparison within Medacta MOTO Patella and Zimmer NexGen Patella in relation to Contact Pressure and Areas according to Test Reports 00812-009634-1 and 00812-007185-1 and Test Protocols IL 07.09.551 and IL 07.09.461. *Test report B4*
  - Wear Behaviour MOTO PFJ & MOTO Patella. *Test report B5*

- *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.

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the MOTO PFJ System is as safe and effective as the predicate devices. Therefore, it is concluded that the MOTO PFJ System is substantially equivalent to the predicate device.

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