DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 3, 2017

Medacta International SA
% Elizabeth Wheeler
Manager, Regulatory Affairs
Mapi USA, Inc
2343 Alexandria Drive, Suite 100
Lexington, Kentucky 40504

Re: K162084
Trade/Device Name: Moto 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: November 16, 2016
Received: November 17, 2016

Dear Elizabeth Wheeler:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Lori A. Wiggins -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K162084

Device Name
MOTO™ Partial Knee System

Indications for Use *(Describe)*
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 side 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.

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1 510(k) Summary

Applicant/Sponsor: Medacta International SA
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Date Prepared: July 26, 2016
Date Revised: November 16, 2016

DEVICE INFORMATION

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

PREDICATE DEVICE INFORMATION

Primary predicates:

510(k)	Product	510(k) Holder
K073175	Journey	Smith & Nephew

Additional predicates:

510(k)	Product	510(k) Holder
K102069	Journey	Smith & Nephew
K033363	UNI	Zimmer

DEVICE DESCRIPTION

The MOTO™ Partial Knee System is a knee prosthesis designed for cemented use in medial compartment 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 post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty. 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™ Partial Knee System implants are offered sterile (via gamma irradiation or ethylene oxide), are intended for single use only, and may not be re-sterilized.

The Anatomic Femoral Component (cemented) is anatomically shaped and designed with two (2) fixation pegs for sizes 1 to 7 and three (3) fixation pegs for sizes 8 to 10. Available in ten (10) sizes (1 - 10), the femoral component is offered in both Right Medial (RM) and Left Medial (LM) options for each size.

The Medial Fixed Tibial Insert has a fixed design and is available in five (8) sizes (1 – 8). Each size is offered in six (6) levels of thickness (8, 9, 10, 11, 12, 14 mm).

The Medial Fixed Tibial Tray (cemented) has a fixed bearing design with one fixation keel and peg to ensure primary stability. Available in five (8) sizes (1 – 8), the Medial Fixed Tibial Tray are offered in both Right Medial (RM) and Left Medial (LM) options for each size.

INDICATIONS FOR USE

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 side 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.

Discussion:

The Indications for Use Statement is similar to the predicate device. 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.

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

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

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

PERFORMANCE TESTING

The following studies were performed to support substantial equivalence:

- Fatigue under dynamic physiological loads according to ASTM F1800
- Excessive wear according to ASTM F2083
- Sterilization validation in accordance with ANSI/AAMI/ISO 11137-1:2006, ANSI/AAMI/ISO 11137-2:2006 and ISO 11135-1:2007
- Accelerated and real time aging
- Packaging validation
- Limulus Amebocyte Lysate (LAL) testing was evaluated to establish the device meets pyrogen limit specifications.

Conclusion:

Based on the above information, the MOTO™ Partial Knee System can be considered substantially equivalent to the identified predicate devices.