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

Re: K202730
Trade/Device Name: Quadra-P
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH, KWY, LZY, LPH, JDI
Dated: November 25, 2020
Received: November 27, 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,

for

Vesa Vuniqi
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)*

K202730

Device Name
Quadra-P

Indications for Use *(Describe)*

The hip prostheses QUADRA-P and QUADRA-P collared are designed for cementless use in total or partial hip arthroplasty, for primary or revision surgery. The hip prosthesis QUADRA-P cemented is designed for cemented use in total or partial hip arthroplasty in primary or revision surgery. Hip replacement is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthrosis, traumatic arthritis, rheumatoid polyarthritis or congenital hip dysplasia
- Avascular necrosis of the femoral head
- Acute traumatic fracture of the femoral head or neck
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, partial hip arthroplasty, hip resurfacing replacement or total hip 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 and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director of Quality and Regulatory, Medacta USA
Date Prepared: September 15, 2020
Date Revised: November 25, 2020

II. Device

Device Proprietary Name:	Quadra-P
Common or Usual Name:	Femoral Stems
Classification Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Primary Product Code:	LZO
Secondary Product Codes	MEH, KWY, LZY, LPH, JDI
Regulation Number:	21 CFR 888.3353, 21 CFR 888.3390, 21CFR 888.3360, 21 CFR 888.3358
Device Classification	II

III. Predicate Device

Primary predicate device:

- Quadra-P, K181254, Medacta International SA
- Quadra-P Extension, K192827, Medacta International SA

The following devices are referenced:

- AMIStem-H Proximal Coating, K121011, Medacta International SA
- AMIStem-H Proximal Coating, AMIStem-P and AMIStem-P Collared, K173794, Medacta International SA
- Medacta Total Hip Prosthesis System – Quadra C (also referred to as “Quadra C”), K083558, Medacta International SA

IV. Device Description

The Quadra-P implant subject of this submission is a line extension to the currently cleared Quadra-P implants (K181254 and K192827).

The stem subject of this submission is a range extension of the Quadra-P Short Neck Standard stem cleared under K192827.

The Quadra-P implant subject of this submission is the Quadra-P Short Neck STD stem size 00, a coated cementless stem, commercial reference 01.12.249.

The Quadra-P implants are part of the Medacta Total Hip Prosthesis system.
The Medacta Total Hip Prosthesis system consists of femoral stems, modular femoral heads, and acetabular components.

Quadra-P family includes cementless and cemented stems.
Quadra-P, Quadra-P Short Neck, and Quadra-P Collared implants are cementless stems made with a titanium alloy substrate (Ti6Al7Nb) according to ISO 5832-11 Second Edition 2014-09-15: Implants for Surgery – Metallic Materials – Part 11: Wrought Titanium 6–Aluminium 7-Niobium Alloy. The femoral stems have a Eurocone (12/14 taper) and polished necks.

Quadra-P, Quadra-P Short Neck, and Quadra-P Collared implants have an air plasma sprayed Titanium Y367 and Hydroxyapatite Osprovit (HA) dual layer coating on the proximal end of the shaft. The dual coating covers approximately 50% of the stem length. The distal part of the stem is coated with hydroxyapatite after sandblasting.

Also included in Quadra-P family, are the Quadra-P Cemented stems manufactured from High Nitrogen Stainless Steel.

The acetabular components consist of metal cups and liners made of ultra-high molecular weight polyethylene (UHMWPE) or Highcross highly crosslinked ultra-high molecular weight polyethylene (HXUHMWPE). Acetabular components include the Mpact DM (K143453), VersafitCup (K083116 and K092265), VersafitCup CC Trio (K103352), Mpact (K103721 and K132879), Mpact 3D Metal (K171966), and Medacta Bipolar Head (K091967).

The Quadra-P implants can be combined with the CoCr Ball Heads (K072857 and K080885), Endo Head (K111145), MectaCer Biolox Option Heads (K131518), or MectaCer BIOLOX® Forte (K073337) or MectaCer BIOLOX® Delta Femoral Heads (K112115).

V. Indications for Use

The hip prostheses QUADRA-P and QUADRA-P collared are designed for cementless use in total or partial hip arthroplasty, for primary or revision surgery. The hip prosthesis QUADRA-P cemented is designed for cemented use in total or partial hip arthroplasty in primary or revision surgery.
Hip replacement is indicated in the following cases:

• Severely painful and/or disabled joint as a result of arthrosis, traumatic arthritis, rheumatoid polyarthritis or congenital hip dysplasia
• Avascular necrosis of the femoral head
• Acute traumatic fracture of the femoral head or neck
• Failure of previous hip surgery: joint joint reconstruction, internal fixation, arthrodesis, partial hip arthroplasty, hip resurfacing replacement or total hip arthroplasty

VI. Comparison of Technological Characteristics

The Quadra-P implant subject of this submission and the predicate devices share the following characteristics:

- CCD angle;
- Taper 12/14;
- materials of construction;
- coating;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The Quadra-P implant subject of this submission is technologically different from the predicate devices as follows:

- neck offset;
- stem length;

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:

<u>Non-Clinical Studies:</u>

- PERFORMANCE TEST

    - Range of motion (ROM): EN ISO 21535:2009 Non-Active Surgical Implants - Joint Replacement Implants - Specific Requirements for Hip-Joint Replacement Implants;
    - Fatigue test (FEM): worst case justification regarding the fatigue test of the Quadra-P Short Neck stems according to ISO 7206-4[2010]
    - Fatigue test (FEM): worst case justification regarding the fatigue test of the Quadra-P Short Neck stems according to ISO 7206-6.
    - Pull off force testing: ASTM F2009-00 (Reapproved 2011) Standard Test Method For Determining The Axial Disassembly Force Of Taper Connections Of Modular Prostheses.

- DESIGN VALIDATION

    - Comparison between the new Quadra-P Short Neck stem family and the current Quadra-P stems

- COATING TEST
    - ISO 13779-1 Second Edition 2008-10-01 Implants for Surgery - Hydroxyapatite - Part 1: Ceramic Hydroxyapatite; and
    - ASTM F1147-99 Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings.

- PYROGENICITY

    - Bacterial Endotoxin Test (LAL test) was conducted according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and pyrogen test according to USP chapter <151> for pyrogenicity determination; and
    - the subject devices are not labeled as non-pyrogenic or pyrogen free.

Clinical Studies

- No clinical studies were conducted

VIII. Conclusion

Based on the above information, the Quadra-P implants new size 00 Standard version, is 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 Quadra-P range extension implant is as safe and effective as the predicate devices, Quadra-P (K181254, Medacta International SA) and Quadra-P extension, (K192827, Medacta International SA)) (Only Cementless stems).