April 8, 2021

Medacta International SA
% Chris Lussier
Senior Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 83118

Re: K210062
Trade/Device Name: Mectaplug PE II
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: JDK
Dated: January 8, 2021
Received: January 11, 2021

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,

Vesa Vuniqi -S

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)*
K210062

Device Name
Mectaplug PE II

Indications for Use *(Describe)*
MectaPlug PE II is an intramedullary cement restrictor, designed to seal the intramedullary canal prior to cementation in total or partial hip arthroplasty, for primary or revision surgery.

Total hip arthroplasty 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

Partial hip arthroplasty is indicated in the following cases:

• Acute traumatic fracture of the femoral head or neck
• Non-union of femoral neck fracture
• Avascular necrosis of the femoral head
• Primary pathology involving the femoral head, but with a non-deformed acetabulum

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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3.0 510(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 of Quality and Regulatory, Medacta USA
Date Prepared: January 8, 2021
Date Revised: April 8, 2021

II. Device

Device Proprietary Name:	Mectaplug PE II
Common or Usual Name:	Prosthesis, Hip, Cement Restrictor
Classification Name:	Surgical Mesh
Primary Product Code:	JDK
Regulation Number:	21 CFR 878.3300
Device Classification	II

III. Predicate Device

Primary predicate device:

- Tecres Cement Restrictors, K021765, Tecres S.p.A.

Reference predicate:

- Femoral Cement Restrictors, K800144, Biomet Inc.
- BUCK cement restrictors, K791125, Smith & Nephew
- Quadra P, K192827, Medacta International
- GMK Full PE Tibial components, K131310, Medacta International SA

IV. Device Description

MectaPlug PE II is an intramedullary cement restrictor (plug), used to seal the intramedullary canal prior to cementation in total or partial hip arthroplasty. MectaPlug PE II prevents the cement from flowing down the diaphysis, thereby facilitating cement pressurization. MectaPlug PE II is composed of UHMWPE (ISO 5834-2) with a radiopaque stainless steel wire (ISO 5832-1).

MectaPlug PE II is positioned distal to the stem tip preventing cement from being displaced distally in the canal and increasing the intramedullary pressure at the bone-cement interface during insertion of the stem. A radio marker is included in the tip of the Medacta cement restrictor.

MectaPlug PE II has 6 discs divided in several leaves by oblique cuts and a central peg. The MectaPlug PE II device is available in the following sizes: S (Ø 8 to Ø 11), M (Ø 12 to Ø 15), L (Ø 16 to Ø 20), XL (Ø 21 to Ø 25), XXL (Ø 26 to Ø 30).

MectaPlug PE II is made in UHMWPE according to ISO 5834-2 Implants for surgery -- Ultra-high-molecular-weight polyethylene Moulded forms and with a radiopaque wire in AISI 316LVM according to ISO 5832-1 Implants for surgery — Metallic materials — Part 1: Wrought stainless steel.

Mectaplug PE II implants are provided sterile and in single-use packages.

V. Indications for Use

MectaPlug PE II is an intramedullary cement restrictor, designed to seal the intramedullary canal prior to cementation in total or partial hip arthroplasty, for primary or revision surgery.

Total hip arthroplasty 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

Partial hip arthroplasty is indicated in the following cases:

- Acute traumatic fracture of the femoral head or neck
- Non-union of femoral neck fracture
- Avascular necrosis of the femoral head
- Primary pathology involving the femoral head, but with a non-deformed acetabulum

VI. Comparison of Technological Characteristics

The subject device and the predicate device share the following characteristics:

- shape;
- dimension;
- material of construction (UHMWPE)

The subject device is technologically different from the predicate device as follows:

- radiopaque wire in AISI 316LVM
- sizes

VII. Performance Data

Testing was conducted according to written protocols with acceptance criteria. The following mechanical studies were performed in support of a substantial equivalence determination:

Non-Clinical Studies:

- Risk that the cement restrictors are inadequate for femoral canal shape and not suitable for AMIS approach, Design Validation Report Nr: B1 and Design Validation Report Nr: B3
- Risk that Product range is not adequate to cover all the intended population, Design Validation Report Nr: B1
- Risk of breakage of highly stressed parts, Design Validation Report Nr: B2
- Shelf Life – Characterization of Medacta's Highly Crosslinked UHMWPE, Test Report
- 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
    - the subject devices are not labeled as non-pyrogenic or pyrogen free

Clinical Studies

- No clinical studies were conducted

VIII. Conclusion

The information provided with this submission supports that the subject devices are substantially equivalent to the identified predicate devices.

Substantial equivalence has been demonstrated through a comparison of intended use, indications for use, design and technological characteristics, as well as performance evaluations.