September 22, 2021

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

Re: K210263
Trade/Device Name: Mpres Neck Preserving Stem
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
Dated: August 16, 2021
Received: August 17, 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,

Limin Sun, Ph.D.
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)*

K210263

Device Name
Mpres Neck Preserving Stem

Indications for Use *(Describe)*

The Mpres stem is a cementless neck preserving stem designed for use in total or partial hip arthroplasty for primary or revision surgery.

Total Hip Arthroplasty with the Mpres stem 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.
• Failure of previous hip surgery:
o Conservative hip surgery,
o Internal fixation,
o Arthrodesis,
o Hip resurfacing replacement.

Partial hip arthroplasty with the Mpres stem is indicated in the following cases:

• Acute traumatic fracture of the femoral head.
• 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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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 21, 2021

II. Device

Device Proprietary Name:	Mpres Neck Preserving Stem
Common or Usual Name:	Hip Prosthesis
Classification Name:	*Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis*
Primary Product Code:	LZO
Secondary product code	MEH
Regulation Number:	21 CFR 888.3353
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following primary predicate device:

- MiniHip, K083312, Corin USA

In addition the following reference devices are cited within the submission:

- MiniHip, K111046, Corin USA
- SMS Cementless Stem Extension, K201673, Medacta International SA
- SMS Cementless Stem, K181693, Medacta International SA
- MiniMAX, K170845, Medacta International SA

IV. Device Description

The Mpres Neck Preserving Stem is a cementless short femoral stem intended to be used in total or partial hip arthroplasty for primary or revision surgery with minimally invasive hip replacement techniques.

The Mpres Neck Preserving Stem is made of titanium alloy (Ti6Al7Nb) according to ISO 5832-11 and coated with Titanium plasma spray according to ASTM F1580 and Hydroxyapatite in compliance with ASTM F1185. It is available in 12 sizes (sizes 3-14) for each neck variation configuration: a standard 130° CCD angle or an high offset 123° CCD angle.

Identically to the reference devices (SMS Cementless Stem - K201673 and K181963), the Mpres Neck Preserving Stem can be combined with the CoCr ball head (K072857, K080885 and K103721), Endo Head (K111145), the MectaCer BIOLOX® forte (K073337), MectaCer BIOLOX® Delta Femoral Heads (K112115) or MectaCer BIOLOX® Option Heads (K131518).

V. Indications for Use

The Mpres stem is a cementless neck preserving stem designed for use in total or partial hip arthroplasty for primary or revision surgery.
Total Hip Arthroplasty with the Mpres stem 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.
- Failure of previous hip surgery:
    - Conservative hip surgery,
    - Internal fixation,
    - Arthrodesis,
    - Hip resurfacing replacement.

Partial hip arthroplasty with the Mpres stem is indicated in the following cases:

- Acute traumatic fracture of the femoral head.
- Avascular necrosis of the femoral head.
- Primary pathology involving the femoral head but with a non-deformed acetabulum.

VI. Comparison of Technological Characteristics

The Mpres Neck Preserving Stem implants and the predicate device (Corin MiniHip, K083312 and K111046) are similar in the following characteristics:

- shape and design;
- cementless use;
- CP-Ti and HA coating;
- mirror polishing surfaces;
- biocompatibility;
- device usage;
- gamma radiation sterile; and
- packaging.

The Mpres Neck Preserving Stem implants differ from the predicate device (Corin MiniHip, K083312 and K111046) as follow:

- sizes;
- stem length;
- neck offset; and
- materials.

Discussion

The shape and design, the indications for use as well as the coating, device usage, biocompatibility, sterility and shelf life are similar to the predicate devices (Corin MiniHip, K083312 and K111046). Medacta International SA has not made any change to the materials and coating, device usage, biocompatibility, sterility, shelf life, and packaging of the subject devices respect to the reference devices (K201673, K1819693 and K170845).

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 Mpres Neck Preserving Stem 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 were provided in support of the substantial equivalence determination:

Non-Clinical Studies

- *DESIGN VALIDATION*
  - Mpres Sawbone Design validation report
  - Plastic Stem Impactor, cadaveric evaluation

- *CHARACTERIZATION TESTING*
  - Pull-Off Test On CoCr Femoral Head according to Test Protocol IL 07.09.033 (per ASTM F2009-00:2005, ISO 5832-9:2007 and ISO 5832-12:1996), EndoLab Test Report, No.: 167.090722.10.1309 (per ISO 7206-10:2003), CeramTec AG Test Reports 3128 (per ISO 5832-11 and ISO 7206-10) and 3300 (per ISO 7206-10).
  - Mpres evaluation of the ROM (per EN ISO 21535:2009).
  - Mpres Neck and Shaft Fatigue test according to Test Protocol IL 07.09.001 (per ISO 7206-6:2013 and ISO 7206-4:2010), Fatigue test worst case rationales (Neck worst case per ASTM F2068-15, ASTM F2996-13, ISO 5832-11 and ISO 7206-6:2013) (Shaft worst case per ASTM F2068-15, ISO 7206-4:2010, ASTM F2996-13 and ISO 5832-11), Endolab Test Report 167_201005_10_3284-part1-rev0 (per ISO 7206-6:2013), Accentus Test Report OTC357 Final Report Medacta and Straight Cantilever Test Report (per ISO 7206-4:2010).

- Mpres Coating validation rationale (per ISO 5832-11).
- Mpres femoral stems – Fretting Corrosion Rationale (per ISO 5832-11 and ISO 21534).

- *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

It is demonstrated in the submission that the Mpres Neck Preserving Stem implants are substantially equivalent to the predicate devices.