September 27, 2019

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

Re: K192352
Trade/Device Name: MiniMAX
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
Dated: August 28, 2019
Received: August 29, 2019

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
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)*
K192352

Device Name
MiniMax

Indications for Use *(Describe)*
The hip prosthesis MiniMAX is designed for cementless 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 arthritis, 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, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

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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3.0 510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director Medacta International SA
Date Prepared: August 28, 2019
Date Revised: September 26, 2019

II. Device

Device Proprietary Name:	MiniMAX
Common or Usual Name:	Hip Prosthesis
Classification Name:	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented
Primary Product Code:	LZO
Secondary Product Code:	MEH, KWY, LZY
Regulation Number:	21 CFR 888.3353, 21 CFR 888.3390, 21 CFR 888.3360
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- MiniMAX, K170845, Medacta International SA

IV. Device Description

MiniMax anatomical stems are coated cementless stems intended to be used in total or partial hip arthroplasty in primary or revision surgery.

The anatomical design of the MiniMax stems results in a 9° anteversion of the neck which is mirror polished with 12/14 Eurocone taper and a 127° neck-shaft angle. The macrostructures are negative medially and positive laterally which increases the contact area. The lateral flare is rounded and

non-invasive. The MiniMAX stems' distal tip has a 5° curvature to follow the contours of the femoral canal to aid in the insertion and avoiding distal interference.

MiniMAX stems can be combined with the CoCr ball heads (K072857, K080885 and K103721), Endo Head (K111145) or with the MectaCer BIOLOX® Forte (K073337), MectaCer BIOLOX® Delta Femoral Heads (K112115) or MectaCer BIOLOX® Option Heads (K131518).

MiniMAX stems are made of Titanium Aluminum Niobium Alloy (Ti-6Al-7Nb). The surface treatment consists of titanium plasma spray coating, Ra 300µm, in the proximal 2/3 of the shaft to improve proximal fixation and HA (Hydroxyapatite) coating, Ra 80µm, along the entire length of the shaft.

This submission seeks add Size 9 left and right anatomical stems to the currently marketed MiniMAX product line.

V. Indications for Use

The hip prosthesis MiniMAX is designed for cementless 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 arthritis, 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, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

VI. Comparison of Technological Characteristics

The subject and predicate MiniMAX stems share the following characteristics:

- taper;
- substrate material;
- coating;
- device usage;
- CCD angle;
- sterility;
- shelf life; and
- packaging.

The subject devices are technologically different from the predicate devices with respect to size, length, and neck offset.

Discussion
As seen above, the subject MiniMAX stems are substantially equivalent to the predicate devices in terms of design, substrate material, coating, device usage, sterility, shelf life, and packaging.

The additional size (longer stem length and larger neck offset) does not introduce a new worst case with respect to biomechanical or clinical performance. The additional size has been designed in order to increase the product range. This technological difference does not raise new questions of safety or effectiveness and a comparison evaluation shows there are no new risks associated with the subject device design.

VII. Performance Data

The predicate MiniMAX stems (cleared under K170845)) were tested using the worst-case device for each of the following tests:

- range of motion (ROM): EN ISO 21535:2009 Non-Active Surgical Implants — Joint Replacement Implants — Specific Requirements for Hip-Joint Replacement Implants;
- fatigue testing: ISO 7206-4 Third Edition 2010-06-15 Implants for Surgery - Partial and Total Hip Joint Prostheses - Part 4: Determination of Endurance Properties and Performance of Stemmed Femoral Components [Including AMENDMENT 1 (2016)];
- fatigue testing: ISO 7206-6 Second Edition 2013-11-15 Implants for Surgery - Partial and Total Hip Joint Prostheses - Part 6: Determination of Endurance Properties of Head and Neck Region of Stemmed Femoral Components;
- static fatigue testing: ISO 7206-10:2003 Implants for Surgery -- Partial and Total Hip-Joint Prostheses -- Part 10: Determination of Resistance To Static Load of Modular Femoral Heads;
- pull off force testing: ASTM F2009-00 (Reapproved 2011) Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses;
- coating characterization testing; and
- pyrogenicity per USP <85> and USP <151>.

The subject devices do not represent a new worst case when compared to the previously cleared devices (K170845). Additional evaluation and finite element analysis of stem and neck fatigue testing of the subject device is provided (ISO 21535).

The data and information provided in K170845 support the conclusion that the subject MiniMAX devices are safe and effective and conform to applicable standards and FDA guidance.

VIII. Conclusion

Based on the above information, the subject MiniMAX stems can be considered substantially equivalent to the identified predicate device.

Substantial equivalence has been demonstrated through a comparison of intended use, design, and technological characteristics, as well as performance evaluations. The subject MiniMAX implants are as safe and effective as the predicate devices, Medacta's MiniMAX stems (cleared under K170845).