DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

August 8, 2017

Re: K170845
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: July 10, 2017
Received: July 11, 2017

Dear Ms. Rose:

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,

Mark N. Melkerson -S

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)*

K170845

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.

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3.0 510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager
Consultant: Elizabeth Rose, Regulatory Affairs, Manager, Medical Devices, Mapi USA, Inc.
Date Prepared: March 21, 2017
Date Revised: August 4, 2017

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
FDA Product Code(s):	LZO, MEH, KWY, LZY
Regulation Number:	21 CFR 888.3353, 21 CFR 888.3390, 21 CFR 888.3360
Device Classification	2

III. Predicate Device

Substantial equivalence is claimed to the following devices:
Primary Predicate:

- ABG III Monolithic Hip Stem (Also known as Anato Hip Stem), K123604, Howmedica Osteonics Corp.

Additional Predicates

- MasterLoc Stem, K151531, Medacta International SA

IV. Device Description

The purpose of this submission is to gain clearance for the new MiniMAX, which are anatomical HA 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 9º 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 have 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.

MiniMAX stems are similar to predicate devices Howmedica Osteonics' ABG III Monolithic Hip Stem (K123604) and Medacta's MasterLoc Stem (K151531).

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

MiniMAX and the predicate devices share the following characteristics:

- indications for use;
- materials;
- design;
- sterile;
- coating;
- device usage; and
- taper.

MiniMAX is technologically different from the predicate devices as follows:

- lengths; and
- neck angles.

The MiniMAX stems are manufactured with Titanium Aluminum Niobium Alloy (Ti6-Al 7-Nb) according to ISO 5832-11 Second Edition 2014-09-15: Implants for Surgery – Metallic Materials

– Part 11: Wrought Titanium 6–Aluminium 7-Niobium Alloy with a Titanium Y367 + Hydroxyapatite "Osprovit®" coating.

Due to the extensive history of safe use in legally US-marketed medical devices, currently marketed devices made of the same material (Titanium Aluminum Niobium Alloy (Ti6-Al 7-Nb) per ISO 5832-11 Second Edition 2014-09-15: Implants for Surgery – Metallic Materials – Part 11: Wrought Titanium 6–Aluminium 7-Niobium Alloy) with the same coating following recognized standards and following identical or similar manufacturing processes, additional biocompatibility testing was deemed unnecessary.

Discussion
As seen above, the technological differences between the subject and predicate devices do not raise new questions of safety and effectiveness. MiniMAX is the same or similar to the predicate devices in terms of intended use, materials of construction, design, coating, taper, device usage, and sterility. Based on the comparison of technological characteristics and performance data provided within this submission, the data supports the substantial equivalence of MiniMAX to the identified predicate devices.

VII. Performance Data

The following mechanical tests are being provided in support of a substantial equivalence determination. Based on the risk analysis, testing was conducted to written protocols with acceptance criteria that were based on standards and FDA guidance documents.

Non-Clinical Studies

- Performance 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 Tests
  - Coating characterization testing was performed.
- Pyrogenicity
  - The Bacterial Endotoxin Test (LAL test) was conducted according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and the 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 above supports that MiniMAX is as safe and effective as the predicate devices. Therefore, it is concluded that MiniMAX is substantially equivalent to the predicate devices.

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