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

March 2, 2021

Re: K203755
Trade/Device Name: Shoulder System - TiNbN Coating
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, MBF, HSD
Dated: December 21, 2020
Received: December 23, 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,

Michael Owens
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)*

K203755

Device Name
Shoulder System - TiNbN Coating

Indications for Use *(Describe)*

The Medacta Anatomic Shoulder Prosthesis is indicated for treatment of humeral fractures and for primary or revision total shoulder replacement in patients with an intact or reparable rotator cuff shoulder joint, severe arthropathy or a previously failed joint replacement. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary for the device to offer full function in vivo. The glenoid component is intended for cemented application. The humeral stems are intended for cemented or cementless use.

The Medacta Anatomic Shoulder Prosthesis – Short Humeral Diaphysis is indicated for primary total shoulder replacement in patients with an intact or reparable rotator cuff shoulder joint, severe arthropathy. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary for the device to offer full function in vivo. The glenoid component is intended for cemented application. The humeral short stem is intended for cementless use.

The Reverse Shoulder Prosthesis is indicated for treatment of humeral fractures and for primary or revision total shoulder replacement in patients with a grossly deficient rotator cuff shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff shoulder joint. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stems are intended for cemented or cementless use.

The Reverse Shoulder Prosthesis- Short Humeral Diaphysis is indicated for primary total shoulder replacement in patients with grossly deficient rotator cuff shoulder joint with severe arthropathy. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral short stem is intended for cementless use.

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: December 22, 2020
Date Revised: March 2, 2021

II. Device

Device Proprietary Name:	Shoulder System - TiNbN Coating
Common or Usual Name:	Shoulder Prosthesis
Classification Name:	Shoulder joint metal/polymer/metal nonconstrained or semiconstrained porous-coated uncemented prosthesis Shoulder joint metal/polymer semi-constrained cemented prosthesis Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Primary Product Code:	PHX
Secondary Product Code:	KWS, MBF, HSD
Regulation Number:	21 CFR 888.3660, 21CFR 888.3670, 21 CFR 888.3690
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary predicate device:

- Lateralized Glenosphere (Medacta Shoulder Reverse System), K193175, Medacta International

Additional predicate device:

- Glenosphere (Medacta Shoulder Reverse System), K170452, Medacta International
- Humeral Head (Medacta Shoulder Anatomical System), K170910, Medacta International
- GMK Total Knee System (TiNbN) Coating, K202684, Medacta International

- Medacta Shoulder System Short Humeral Diaphysis, K180089, Medacta International

IV. Device Description

The Shoulder System - TiNbN Coating is a line extension to the Shoulder System to provide a larger product offering. The subject devices are marketed as individually packaged humeral head, Glenosphere and lateralized Glenosphere components.
Shoulder System - TiNbN Coating includes the following implants:

- Humeral Head TiNbN Coating (10 sizes, Ø 40 mm to Ø 58 mm)

- Lateralized Glenosphere TiNbN Coating implants (9 sizes) and

- Glenosphere implants TiNbN Coating subject of this submission are comprised of the following products (9 sizes):
  - Size Ø 32: to be coupled with Medacta Glenoid Baseplate Ø 22 or Ø 24.5mm
  - Size Ø 36: to be coupled with Medacta Glenoid Baseplate Ø 22 or Ø 24.5 or Ø27mm
  - Size Ø 39: to be coupled with Medacta Glenoid Baseplate Ø 24.5 or Ø27mm
  - Size Ø 42: to be coupled with Medacta Glenoid Baseplate Ø 24.5 or Ø27mm

The Glenosphere and Lateralized Glenosphere - TiNbN Coating implants, are manufactured from CoCrMo *ISO 5832-12 (Second Edition 2007-05-01) Implants For Surgery – Part 12: Wrought Cobalt- Chromium-Molybdenum Alloy [Including: Technical Corrigendum 1 (2008)]* with a TiNbN coating, while the Glenosphere screw packed with the implant is made of Ti alloy (Ti-6Al-4V), enhanced with Type-II anodization, according to *ISO 5832-3:2016 Implants For Surgery -Metallic Materials - Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy*.

The Humeral Head - TiNbN Coating implants, are manufactured from CoCrMo *ISO 5832-12 (Second Edition 2007-05-01) Implants For Surgery – Part 12: Wrought Cobalt- Chromium-Molybdenum Alloy [Including: Technical Corrigendum 1 (2008)]* with a TiNbN coating.

V. Indications for Use

The Medacta Anatomic Shoulder Prosthesis is indicated for treatment of humeral fractures and for primary or revision total shoulder replacement in patients with an intact or reparable rotator cuff shoulder joint, severe arthropathy or a previously failed joint replacement. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary for the device to offer full function in vivo. The glenoid component is intended for cemented application. The humeral stems are intended for cemented or cementless use.

The Medacta Anatomic Shoulder Prosthesis – Short Humeral Diaphysis is indicated for primary total shoulder replacement in patients with an intact or reparable rotator cuff shoulder joint, severe arthropathy. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary for the device to offer full function in vivo.

The glenoid component is intended for cemented application. The humeral short stem is intended for cementless use.
The Reverse Shoulder Prosthesis is indicated for treatment of humeral fractures and for primary or revision total shoulder replacement in patients with a grossly deficient rotator cuff shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff shoulder joint. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stems are intended for cemented or cementless use.

The Reverse Shoulder Prosthesis- Short Humeral Diaphysis is indicated for primary total shoulder replacement in patients with grossly deficient rotator cuff shoulder joint with severe arthropathy. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral short stem is intended for cementless use.

VI. Comparison of Technological Characteristics

The Shoulder System - TiNbN Coating and the predicate devices Shoulder System (K170452, K193175, K170910) share the following characteristics:

- indication for use
- design;
- fixation
- substrate material;
- device usage;
- sterility;
- shelf life; and
- packaging.

The Shoulder System - TiNbN Coating differs from the predicate devices Shoulder System (K170452, K193175, K170910) in relation to the coating only as the subject devices have a TiNbN coating while the predicate devices have no coating.

The Shoulder System - TiNbN Coating has the same coating cleared for GMK Total Knee System (TiNbN) Coating, K202684.

The Shoulder System Short Humeral Diaphysis (previously cleared via K180089) is utilized with the afore mentioned shoulder system components.

VII. Performance Data

Based on the risk analysis, testing was conducted according to written protocols. The following tests are being provided in support of a substantial equivalence determination:

Non-Clinical Studies:

- PERFORMANCE TESTING

Anatomical humeral head TiNbN coated

- Pull-off testing, according to Medacta Test Protocol IL 07.09.631 rev 0 and Medacta Test Report B.3 and ENDOLAB report 167_200908_60_238-rev 0 part 1
  ASTM F2009-11: Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses

- Fatigue testing, according to Medacta Test Protocol IL07.09.630 rev 0 and Medacta Test Report B.1, and ENDOLAB report: 167_200908_60_238-rev 0 part 2
  ISO 7206-4:2010(E): "Implants for surgery - Partial and total hip joint prostheses - Part 4: Determination of endurance properties and performance of stemmed femoral components."
  "ASTM F1378-17: Standard specifications for shoulder prosthesis"

Glenosphere TiNbN coated

- Fatigue testing, according to Medacta Test Protocol IL07.09.629 rev 0 and Medacta Test Report B.2, and ENDOLAB report: 167_200908_60_239-rev0 167_201002_60_242-rev0

The following performance test was previously conducted on the predicate devices and reviewed as part of the GMK Total Knee System (TiNbN) Coating, K202684:

- Third body wear test

The following performance tests were previously conducted on the predicate devices and reviewed as part of the Shoulder System K170452, K193175, K170910:

- Wear test
- Geometrical Analysis

The following performance tests were previously conducted on the predicate devices and reviewed as part of the Shoulder System K170452, K193175:

- Micromotion assessments

- PYROGENICITY
  - Bacterial Endotoxin Test (LAL test) was conducted 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

- BIOCOMPATIBILITY
  - Biocompatibility assessment and related testing as per *ISO 10993 series and FDA Biocompatibility Guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*

Clinical Studies

- No clinical studies were conducted

VIII. Conclusion

Based on the above information, the Shoulder System - TiNbN Coating implants can be considered 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 Shoulder System - TiNbN Coating implants are as safe and effective as the predicate devices, Shoulder System (K170452, K193175, K170910, and K180089).