December 13, 2019

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

Re: K190738
Trade/Device Name: MyShoulder Placement Guides
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, HSD, MBF
Dated: November 13, 2019
Received: November 14, 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,

for

Michael C. Owens
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)*

K190738

Device Name
MyShoulder™ Placement Guides

Indications for Use *(Describe)*

The MyShoulder guides are intended to be used as guides specifically designed for the anatomy of a single patient. The humeral guide is used to define the level and orientation of the humeral head resection cut. The glenoidal guide is used to position and orient the K-wire that will subsequently guide the glenoidal reaming.
Both anatomical and reverse total joint configurations are acceptable.
Both humeral and glenoid guides are suitable for a delto-pectoral approach only.
MyShoulder Patient-Matched Guides are intended for use with Medacta Shoulder System and its cleared indications for use.
MyShoulder Patient-Matched Guides are intended for single use only.

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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2.0 510(k) Summary

K190738

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
Date Prepared: Mar 21, 2019
Date Revised: November 13, 2019

II. Device

Device Proprietary Name:	MyShoulder™ Placement Guides
Common or Usual Name:	Shoulder Prosthesis System
Classification Name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Primary Product Code:	PHX
Secondary Product Code:	KWS, HSD, MBF
Regulation Number:	21 CFR 888.3660, 21 CFR 888.3690, and 21 CFR 888.3670
Device Classification	II

III. Predicate Device

Substantial equivalence is therefore claimed to the following devices:

- Primary Predicate: BLUEPRINT Patient Specific Instrumentation (K143374), Wright-Tornier

- Reference Device:
- Anatomic Shoulder Prosthesis (K170910), Medacta International SA
- Shoulder Reverse System (K170452), Medacta International SA
- MySpine Pedicle Screw Placement Guides (132788), Medacta International SA

IV. Device Description

The MyShoulder™ Placement Guides are patient specific surgical instruments that allow for guided shoulder implants placement of both Medacta Shoulder Reverse System (K170452) and Medacta Anatomic Shoulder Prosthesis (K170910) and the additional products cleared under K181826 (Glenoid Polyaxial Non-locking screws), K180089 (Short Humeral Stem) and K171058 (Threaded Glenoid Baseplate).

The MyShoulder™ Placement guides uses the patient's CT Scan to perform a 3D planning of the glenohumeral joint replacement surgery. Then, following this planning the humeral and glenoidal guides are created. The MyShoulder™ Placement guides are anatomical guides for a single patient anatomy.

The MyShoulder™ Placement guides subject of this submission are comprised of the following products:

1. MyShoulder™ humeral guide: it will allow to perform an accurate humeral resection
2. MyShoulder™ glenoidal guide: it will provide a precise alignment reference that will guide the glenoidal reaming and final implant positioning.

The MyShoulder™ Placement guides are manufactured from medical grade nylon for sintering (Polyamide PA 12) which is identical to Medacta reference device MySpine Pedicle Screw Placement Guides (132788). The MyShoulder™ Placement guides are single use, external communicating devices with limited (<24 hours) contact duration and are provided in non-sterile version only.

The MyShoulder™ Placement guides are substantially equivalent to BLUEPRINT Patient Specific K143374), Wright-Tornier, Medacta reference devices Shoulder Reverse System (K170452) Anatomic Shoulder Prosthesis (K170910), and MySpine Pedicle Screw Placement Guides (132788).

V. Indications for Use

The MyShoulder guides are intended to be used as guides specifically designed for the anatomy of a single patient. The humeral guide is used to define the level and orientation of the humeral head resection cut. The glenoidal guide is used to position and orient the K-wire that will subsequently guide the glenoidal reaming.
Both anatomical and reverse total joint configurations are acceptable.
Both humeral and glenoid guides are suitable for a delto-pectoral approach only.
MyShoulder Patient-Matched Guides are intended for use with Medacta Shoulder System and its cleared indications for use.
MyShoulder Patient-Matched Guides are intended for single use only.

VI. Comparison of Technological Characteristics

MyShoulder glenoid guides are substantially equivalent to Wright-Tornier BLUEPRINT Patient Specific Instrumentation (K143374) for what concerns indications for use, contraindications, design, material and manufacturing process.

MyShoulder guides have substantially equivalent indications for use and contraindications of the reference predicate devices Medacta Shoulder Reverse System (K170452) and Medacta Anatomic Shoulder Prosthesis (K170910).
The technological characteristics including materials, contact duration, software, manufacturing process, device usage, packaging, labeling, and shelf-life of the MyShoulder™ Placement guides are similar to those of the reference device MySpine Pedicle Screw Placement Guides (132788).

The safety and effectiveness of the MyShoulder™ Placement guides are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

VII. Performance Data

Risks were identified based on the proposed design and testing was conducted to mitigate those risks. Based on the risk analysis, testing was conducted according to written protocols with acceptance criteria. The following performance data was provided in support of the substantial equivalence determination:

Non-Clinical Studies:

- Characterization Tests
  - Cadaver Lab – Test Report 1;
  - Surgical Evaluation – Test Report 2; and
  - MyShoulder accuracy and positioning variability – cadaver test – Test Report 4
  - MyShoulder accuracy test – Test Report 5

- Performance Tests
  - Effects of the Sterilization on the geometry of the MyShoulder Glenoidal Guide – Test Report 3
  - Wear Test, according to RPQ-01.028.009

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

Based on the above information, the MyShoulder™ Placement guides are substantially equivalent to the identified predicate and reference devices.

Substantial equivalence has been demonstrated through a comparison of indication for use, design, and technological characteristics, as well as performance evaluations. The MyShoulder™ Placement guides are as safe and effective as the predicate device BLUEPRINT Patient Specific Instrumentation (K143374), Wright-Tornier and the reference devices Medacta Shoulder Reverse System (K170452), Medacta Anatomic Shoulder Prosthesis (K170910) and MySpine Pedicle Screw Placement Guides (K132788).