Medacta International S.A.
% Christopher Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
6386 Global Drive, Suite 101
Memphis, Tennessee 38141

January 30, 2025

Re: K241292
Trade/Device Name: MyShoulder Planner (5.3SSWPL)
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, QHE, LLZ
Dated: May 8, 2024
Received: December 27, 2024

Dear Christopher 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Farzana Sharmin -S Digitally signed by Farzana Sharmin -S
Date: 2025.01.30 13:40:58 -05'00'

Farzana Sharmin, PhD
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241292

Device Name

MyShoulder Planner (5.3SSWPL)

Indications for Use *(Describe)*

The MyShoulder Planner software is a medical device intended for use by surgeons as a preoperative planning tool for total shoulder replacement surgery in skeletally mature individuals.
The MyShoulder Planner software is specifically designed to support the planning of the humeral and glenoid components in a total shoulder replacement using Medacta Shoulder System prosthesis. The MyShoulder Planner software should not be used for diagnostic purposes.
The MyShoulder Planner software processes CT scan images in DICOM format to allow surgeons to visualize, measure, and reconstruct anatomic data. These features enable surgeons to make decisions on implant size and positioning, including the ability to annotate anatomical structures.
The MyShoulder Planner software leads to the generation of patient-specific planning reports, which summarize the preliminary decisions regarding implant size and positioning.
The MyShoulder Planner software allows the surgeons to request the MyShoulder patient matched guides according to the pre-surgical plan.

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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510(k) Summary

I. Submitter

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Primary Contact: Chris Lussier, Senior Director, Quality and Regulatory, Medacta USA
Applicant Contact: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Date Prepared: May 08, 2024
Date Revised: January 30, 2025

II. Device

Device Proprietary Name:	MyShoulder Planner (5.3SSWPL)
Common or Usual Name:	Prosthesis, shoulder, semi-constrained, metal/polymer cemented
Classification Name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Primary Product Code	KWS
Secondary Product Code	LLZ, QHE
Regulation Number:	21 CFR 888.3660
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following primary predicate device:

- Blueprint Patient Specific Instrumentation, K203315, Tornier SAS

IV. Reference device

- MyShoulder Placement Guides, K190738, Medacta International

V. Device Description

The MyShoulder Planner is a software designed to create patient-specific preoperative plans based on CT scans. It is used to visualize the effect of different device choices and positioning options on the patient's shoulder joint biomechanics. It allows the surgeon to preoperatively plan the humeral and glenoid components in total shoulder replacement after the segmentation of a 3D model of the patient's anatomy that can be performed automatically by the software, which uses machine learning algorithms, or manually by a designated Medacta engineer.

After the planning, through the software, the user can request patient-matched guides as well as intraoperative guidance system compatible file.

VI. Indications for Use

The MyShoulder Planner software is a medical device intended for use by surgeons as a preoperative planning tool for total shoulder replacement surgery in skeletally mature individuals.
The MyShoulder Planner software is specifically designed to support the planning of the humeral and glenoid components in a total shoulder replacement using Medacta Shoulder System prosthesis. The MyShoulder Planner software should not be used for diagnostic purposes.
The MyShoulder Planner software processes CT scan images in DICOM format to allow surgeons to visualize, measure, and reconstruct anatomic data. These features enable surgeons to make decisions on implant size and positioning, including the ability to annotate anatomical structures.
The MyShoulder Planner software leads to the generation of patient-specific planning reports, which summarize the preliminary decisions regarding implant size and positioning.
The MyShoulder Planner software allows the surgeons to request the MyShoulder patient matched guides according to the pre-surgical plan.

VII. Comparison of Technological Characteristics

The subject MyShoulder Planner and the predicate Blueprint Patient Specific Instrumentation (K203315) are substantially equivalent with respect to the following characteristics:

- design concept/principle of operation/general workflow;
- operative system compatibility;
- input images and related importation method;
- user interface;
- segmentation and landmark acquisition method; and
- measurements output.

The subject MyShoulder Planner only differs from the predicate Blueprint Patient Specific Instrumentation (K203315) with respect to the management of the patient-matched guides since the subject device does not allow guide design inside the software, but enables guides to be ordered as designed by Medacta. This difference does not raise any new issue of safety and effectiveness since the patient-matched guides are designed and managed as per K190738.
Additional minor differences are related to the compatibility of each device with the related companies' systems and implants, but they have no effect on safety and effectiveness as demonstrated by verification and validation activities.

Discussion
The comparison of technological characteristics and performance data provided within the submission supports the substantial equivalence of the subject device respect to the predicate device.

VIII. Performance Data

Based on the risk analysis, verification and validation activities were conducted to written protocols. The following software verification and validations are provided in support of the substantial equivalence determination:

Non-Clinical Studies

- Software verification and validation including segmentation validation
  Automatic segmentation and landmark acquisition performance was adequately verified in comparison to manual segmentation.

Clinical Studies:

- No clinical studies were conducted.

IX. Conclusion

The information provided above supports that the subject device is substantially equivalent to the predicate device.