Precision AI Pty Ltd
Sara Baniadam
Quality and Regulatory Manager
Suite 18, 36 Agnes Street
Fortitude Valley, Queensland
Australia

August 5, 2024

Re: K233992
Trade/Device Name: Precision AI Surgical Planning System (PAI-SPS)
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: QHE, PHX, KWS
Dated: July 5, 2024
Received: July 5, 2024

Dear Sara Baniadam:

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.

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: 2024.08.05 20:01:43 -04'00'

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)*

K233992

Device Name

Precision AI Surgical Planning System (PAI-SPS)

Indications for Use *(Describe)*

Software
The Precision AI Planning Software is intended to be used as a pre-surgical planner for simulation of surgical interventions for shoulder joint arthroplasty. The software is used to assist in the positioning of shoulder components by creating a 3D bone construct of the joint and allows the surgeon to visualize, measure, reconstruct, annotate and edit pre-surgical plan data. The software leads to the generation of a surgery report along with a pre-surgical plan data file which can be used as input data to design the Precision AI Shoulder Guide and Biomodels.

Hardware
The Precision AI Planning System Guides and Biomodels are intended to be used as patient-specific surgical instruments to assist in the intraoperative positioning of shoulder implant components used with total and reverse shoulder arthroplasty by referencing anatomic landmarks of the shoulder that are identifiable on preoperative CT-imaging scans.
The Glenoid Guide is used to place the k-wire and the Humeral Guide is used to place humeral pins for humeral head resection.
The Precision AI Guides and Biomodels are indicated for single use only.

The Precision AI Surgical Planning System is indicated for use on adult patients that have been consented for shoulder joint arthroplasty. Both humeral and glenoid guides are suitable for a delto-pectoral approach only.

The Precision AI Surgical Planning System is indicated for total and reverse shoulder arthroplasty using the following Enovis implant systems and their compatible components:
- AltiVate Anatomic Shoulder System (K162024)
- AltiVate Anatomic Augmented Glenoid (K213387)
- Turon Shoulder System (K111629)
- Reverse Shoulder Prosthesis (K051075, K092873, K111629)

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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1. Submitter

510(k) Sponsor	Precision AI Pty Ltd
Address	Suite 18, 36 Agnes Street, Fortitude Valley, Queensland, 4006, Australia
Correspondence Person	Sara Baniadam Quality and Regulatory Manager
Contact Information	Email: Regulatory@precisionai.com.au
Submission Date	December 18, 2023

2. Subject Device

Proprietary Name	Precision AI Surgical Planning System (PAI-SPS)
Common Name	Surgical Planning Software and Patient Specific Surgical Guide
Classification Name	Single/multiple component metallic bone fixation appliances and accessories.
Regulation Number	21 CFR 888.3660
Regulation Name	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Product Code	QHE
Additional Product Codes	PHX, KWS
Regulatory Class	II

3. Predicate Devices

Substantial equivalence is therefore claimed to the following devices:

- Primary Predicate:
  - Materialise Shoulder System (K212569)
- Secondary Predicate:
  - Medacta MyShoulder Placement Guide (K190738)
- Reference Device:
  - Formus Hip (K213272)
  - PeekMed Web (K222767)

4. Device Description

Precision AI Surgical Planning System (PAI-SPS) is a patient-specific medical device that is designed to be used to assist the surgeon in the placement of shoulder components during total anatomic and reverse shoulder replacement surgery. This can be done by generating a pre-surgical shoulder plan and, if requested

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by the surgeon, by manufacturing a patient-specific guide and models to transfer the surgical plan to surgery.

The device is a system composed of the following:

- a software component, **Precision AI Surgical Planning Software** which will create a 3D construct of the patient's joint for the surgeon to plan the operation preoperatively. The surgeon will be able to visualise the movement of the diseased joint and determine mechanical failings. They will then be able to place the virtual shoulder replacement in different positions and decide which position gives the patient the best result. Once the surgeon has decided on the best position, the software will generate a CAD file for a Patient Specific Guide.

- **Precision AI Surgical Guides,** which are patient-specific guides and models will be manufactured if the surgeon requests patient-specific guides to transfer the surgical plan to surgery. Once the CAD model is generated from the planning software, the model is sent to a 3D printer which will then print the guide out of a biocompatible medical grade Nylon material for sintering (Polyamide-12) which has an established usage for similar application. The specific design of the guide will be customised to the individual patient as well as depending on the particular anatomy it will be applied to.
  Precision AI Patient Specific Guides are intended for single use only.

5. Indications for Use

Software
The Precision AI Planning Software is intended to be used as a pre-surgical planner for simulation of surgical interventions for shoulder joint arthroplasty. The software is used to assist in the positioning of shoulder components by creating a 3D bone construct of the joint and allows the surgeon to visualize, measure, reconstruct, annotate and edit pre-surgical plan data. The software leads to the generation of a surgery report along with a pre-surgical plan data file which can be used as input data to design the Precision AI Shoulder Guide and Biomodels.

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6. Comparison of Technological Characteristics

The Precision AI Surgical Planning System is comprised of Surgical Planning software and physical patient-matched Surgical Guides. Likewise, the primary predicate, **Materialise Shoulder System (K212569),** comprises of surgery planning software and physical surgical guides.

The secondary predicate, **Medacta MyShoulder Placement Guide (K190738),** is a patient-matched Surgical Guide only, similar to Precision AI Surgical Guide.

Precision AI Surgical Guide is substantially equivalent to predicate devices, **Materialise Shoulder System (K212569)** and **Medacta MyShoulder Placement Guide (K190738)** for what concerns indications for use and contraindications as well as technological characteristics including materials, contact duration, manufacturing process, device usage, packaging, labelling, and shelf-life.

Precision AI Surgical Planning Software incorporates non-adaptive machine or deep learning algorithms trained for the purpose of semi-automatic segmentation and landmark identification of image scans similar to the listed reference devices.

7. Performance Data

The following non-clinical performance studies have been conducted on the subject devices:

Characterization tests:

- Biocompatibility Evaluation
- Dimensional Stability Testing Post Cleaning and Sterilisation
- Packaging and Transportation Testing
- Drop (Impact) Testing
- Compression Testing
- Wear (Debris) Testing
- Software Verification and Validation Testing

Performance testing

- Composite Bone Model Testing
- Cadaveric Testing

In addition, a post-market evaluation of a clinical case series of 35 subjects was conducted to evaluate the measurement accuracy of the subject device via post-operative CT. The study was performed in Australia under ethics committee approval and according to GCP.

The non-clinical and clinical performance testing indicates that the subject device is as safe, as effective, and performs as well as the predicate device.

8. Conclusion

Based on the above information, the Precision AI Surgical Planning System is substantially equivalent to the identified predicate device.
Substantial equivalence has been demonstrated through a comparison of indication for use, design, and technological characteristics, as well as performance evaluations.

None of the technological characteristics differences raised any new question of safety and effectiveness, therefore the Precision AI Surgical Planning System is substantially equivalent to the predicate device.