January 21, 2025

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

Re: K243955
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, KWS, PHX
Dated: December 20, 2024
Received: December 23, 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.

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: 2025.01.21 20:06:29 -05'00'

Farzana Sharmin, Ph.D.
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243955

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 implant systems and their compatible components:

Enovis:

- AltiVate Anatomic (K162024, K173073, K193226 (CS Edge))
- AltiVate Anatomic Augmented (K213387, K222592)
- Turon Shoulder System (K111629, K080402, K123982)
- Reverse Shoulder Prosthesis (K051075, K092873, K111629, K100741, K111061, K111735, K041066, K141006)
- AltiVate Reverse (K141990, K172351, K190290)
- AltiVate Reverse Glenoid (ARG) (K233481)

Lima:

- SMR Shoulder System (K161476, K100858, K101263)
- SMR Reverse Shoulder System (K110598)
- SMR 40MM Glenosphere (K142139)
- SMR 3-Pegs Glenoid (K153722, K130642)
- SMR Modular Glenoid (K113254, K143256)
- SMR TT Metal Back Glenoid (K133349)
- SMR Hybrid Glenoid System (K163397)
- SMR Stemless Anatomic (K221758)
- SMR 140° Reverse Humeral Body (K201905)
- SMR TT Augmented Glenoid System (K191746, K200171)
- SMR Lateralized Connectors with screws (K183042)

- SMR TT Augmented 360 Baseplate (K220792)
- SMR TT Hybrid Glenoid (K220792)
- PRIMA Humeral System and SMR Glenosphere Ø42 (K212800)
- PRIMA TT Glenoid (K222427)

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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PRECISION AI

510(k) Summary

1 Applicant Details

Name:	Precision AI Pty Ltd
Address:	Suite 18 36 Agnes Street Fortitude Valley QLD 4006 Australia
Contact Person / Prepared By:	Sara Baniadam
	Quality and Regulatory Manager
	regulatory@precisionai.com.au
Date Prepared:	20-Dec-2024

2 Device Details and Predicate

Device Common Name:	Surgical Planning Software and Patient Specific Surgical Guide
Device Trade Name:	Precision AI Surgical Planning System (PAI-SPS)
Regulation Number:	21 CFR 888.3660
Regulation Name:	Single/multiple component metallic bone fixation appliances and accessories.
Regulatory Class:	II
Panel:	Orthopedic
Classification Product Code:	QHE, PHX, KWS
Predicate Devices:	PAI-SPS (K233992)

PRECISION AI

3 Device Description Summary

The Precision AI Surgical Planning System 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 by the surgeon, by manufacturing a patient-specific guides and models to transfer the plan to surgery. The subject device is a system composed of the following:

- The Precision AI Surgical Planning System Software will create a 3D construct/render of the patient's shoulder joint for the surgeon to plan the operation preoperatively then create a physical Patient Specific Instrument (or Guide), using 3D printing by selective laser sintering. The patient's CT scan images are the design input for this to be created and are auto segmented via a locked, or static, artificial intelligence algorithm. The surgeon can visualise the deformity of the diseased joint, on this 3D render and CT scan images, and determine the inherent deformity of the joint. They are then able to virtually place the artificial implants in an optimal position to correct the measured deformity for that specific patient.

- The Precision AI Guides, which are a patient-specific guide and models that are based on a pre-surgical plan. This pre-surgical plan is generated using the software component. Patient-specific guide and models will be manufactured if the surgeon requests patient-specific guides to transfer the plan to surgery.

4 Intended Use and 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.

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.

PRECISION AI

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 implant systems and their compatible components:

Enovis:

- AltiVate Anatomic (K162024, K173073, K193226 (CS Edge))
- AltiVate Anatomic Augmented (K213387, K222592)
- Turon Shoulder System (K111629, K080402, K123982)
- Reverse Shoulder Prosthesis (K051075, K092873, K111629, K100741, K111061, K111735, K041066, K141006)
- AltiVate Reverse (K141990, K172351, K190290)
- AltiVate Reverse Glenoid (ARG) (K233481)

Lima:

- SMR Shoulder System (K161476, K100858, K101263)
- SMR Reverse Shoulder System (K110598)
- SMR 40MM Glenosphere (K142139)
- SMR 3-Pegs Glenoid (K153722, K130642)
- SMR Modular Glenoid (K113254, K143256)
- SMR TT Metal Back Glenoid (K133349)
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- SMR Stemless Anatomic (K221758)
- SMR 140° Reverse Humeral Body (K201905)
- SMR TT Augmented Glenoid System (K191746, K200171)
- SMR Lateralized Connectors with screws (K183042)
- SMR TT Augmented 360 Baseplate (K220792)
- SMR TT Hybrid Glenoid (K220792)
- PRIMA Humeral System and SMR Glenosphere Ø42 (K212800)
- PRIMA TT Glenoid (K222427)

5 Functioning of the Device

The PAI-SPS generates a pre-surgical plan based on medical imaging data using the PAI-SPS Software. The software allows a qualified surgeon to visualize, measure, reconstruct, annotate, edit and approve pre-surgical plan data, which leads to the generation of a case planning report. The PAI-SPS Software allows for the creation of a glenoid and/or humeral pre-operative plan. If requested by the surgeon, PAI-SPS Guides and Models are designed and manufactured based on the approved glenoid pre-surgical plan. PAI-SPS Guide and Models are patient specific templates which transfer the pre-

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operatively determined pin positioning to the patient intraoperatively assisting the surgeon in positioning glenoid/humeral components used with total and reverse shoulder arthroplasty procedures.

6 Comparison of Technological Characteristics

The Precision AI Surgical Planning System has an equivalent intended use and the same fundamental scientific technology as the predicate device. The subject device's is intended for positioning shoulder components, i.e. glenoid components and humeral components (same as the predicate device).

Software

The subject software device employs similar fundamental technologies as the predicate software device. Technological similarities include:

- Device functionality: The planning functionality, including visualization, measurement, reconstruction, annotation, and editing of pre-surgical plan data, is the same in the subject and predicate device.
- Software technology: The subject device has the same code base as the predicate device and uses the same methods for design verification and validation as the predicate device.

Following technological differences exist between the subject device software and the predicate device software:

The main difference between the subject device and previously cleared predicate device K233992 is the addition of the following **Enovis'** and **Lima's** implant system components in the software component of the subject device for the surgeon to select during the planning stage:

Enovis:

- AltiVate Anatomic (K173073, K193226 (CS Edge))
- AltiVate Anatomic Augmented (K222592)
- Turon Shoulder System (K080402, K123982)
- Reverse Shoulder Prosthesis (K100741, K111061, K111735, K041066, K141006)
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PRECISION AI

- SMR TT Metal Back Glenoid (K133349)
- SMR Hybrid Glenoid System (K163397)
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- SMR TT Hybrid Glenoid (K220792)
- PRIMA Humeral System and SMR Glenosphere Ø42 (K212800)
- PRIMA TT Glenoid (K222427)

The non-clinical performance data has demonstrated that the subject software technological differences between the subject and predicate device do not raise any different questions of safety and effectiveness.

Hardware

The subject device's hardware is substantially equivalent in intended use, design, functionality, operating principles, materials and performance characteristics compared with the predicate device. The main difference between the subject device hardware and the predicate device is the extension of compatibility of the Precision AI Guides and Models with additional Enovis' and Lima's implant systems and their compatible components:

Enovis:

- AltiVate Anatomic (K173073, K193226 (CS Edge))
- AltiVate Anatomic Augmented (K222592)
- Turon Shoulder System (K080402, K123982)
- Reverse Shoulder Prosthesis (K100741, K111061, K111735, K041066, K141006)
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PRECISION AI

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- SMR TT Hybrid Glenoid (K220792)
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- PRIMA TT Glenoid (K222427)

7 Performance Data (non-clinical)

Hardware:

Previous testing for biocompatibility, sterility, cleaning, debris, dimensional stability and packaging are applicable to the subject device. Testing verified that the accuracy and performance of the system is adequate to perform as intended. The stability of the device placement, surgical technique, intended use and functional elements of the subject device are the same as that of the predicate device of Precision AI Surgical Planning System (K233992) and therefore previous cadaver testing and composite bone model testing on the previously cleared device are considered applicable to the subject device.

Software

Software verification and validation were performed, and documentation was provided following the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." This includes verification against defined requirements and validation against user needs.

Design verification and validation testing demonstrated that the PAI-SPS meets all design requirements and is as safe and effective as its predicate device (K233992).

8 Conclusion

Data presented in this submission demonstrates the PAI-SPS is substantially equivalent to the previously cleared PAI-SPS (K233992).

Substantial equivalence has been demonstrated through a comparison of intended use, design and technological characteristics, as well as performance evaluations.