August 18, 2026

AI Planning Logic, Inc.
℅ Jennifer Palinchik
Owner & CEO
Sagemar Medical, LLC
30628 Detroit Rd.
#254
Westlake, Ohio 44145

Re: K261641
Trade/Device Name: Lower Limb AI (LLAI)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: August 10, 2026
Received: August 10, 2026

Dear Jennifer Palinchik:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

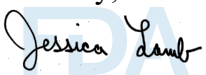
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (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,



Jessica Lamb, PhD
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
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OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K261641 |

Please provide the device trade name(s).

Lower Limb AI (LLAI)

Please provide your Indications for Use below.

The AI Planning Logic (AIPL) Lower Limb AI (LLAI) is software intended for use by orthopedic healthcare professionals in the preoperative planning of knee osteotomy procedures. The device processes CT images of the lower limb to provide:

- Automated segmentation and 3D reconstruction of bony anatomy
- Quantitative measurement of lower limb alignment, including mechanical and anatomical axis angles
- Visualization of anatomical structures and surgical planning outcomes in a virtual 3D environment

The software is intended to be used as an adjunctive tool to support clinical judgment and is not intended to provide diagnostic information or to replace the surgeon's decision-making process.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

# 510(k) Summary - Lower Limb AI (LLAI)

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92

**510(k) SUBMITTER:**
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(440) 935-3282

| | |
|---|---|
| **Device Trade Name:** | Lower Limb AI (LLAI) |
| **Common Name:** | Automated Radiological Image Processing Software |
| **Device Classification Name:** | Medical Image Management and Processing System |
| **Regulation Number:** | 21 CFR 892.2050 |
| **Regulatory Class:** | Class II |
| **Product Code:** | QIH |
| **Review Panel:** | Radiology |
| **Primary Predicate:** | SMART Bun-Yo-Matic CT (K240642) |
| **Reference Predicate:** | PeekMed Web (K252856) |

**Device Description:**
Lower Limb AI (LLAI) is a cloud-based Software as a Medical Device that processes lower-limb CT imaging to support orthopedic preoperative planning. The device receives DICOM CT data, performs automated bone segmentation using locked deep-learning models, identifies anatomical landmarks, generates three-dimensional anatomical reconstructions, and computes quantitative alignment measurements using deterministic mathematical algorithms. Outputs are presented to the clinician for review, confirmation, and use in surgical planning.

The scientific basis for the device includes convolutional neural network image segmentation using deep learning-based segmentation algorithm, geometric modeling of bone surfaces, and established orthopedic alignment principles. Mechanical and anatomical measurements are derived from three-dimensional landmarks, vectors, planes, and joint-center calculations. The software provides automated pelvis, femur, tibia, and ankle-region segmentation; hip, knee, and ankle landmark localization; deterministic angle calculation; STL-based visualization; and repeatable outputs.

LLAI is a software-only device with no patient-contacting components and is accessed through a secure web interface. Significant performance characteristics include:

- Automated segmentation of pelvis, femur, tibia, and ankle regions
- Anatomical landmark localization for hip, knee, and ankle regions
- Deterministic angle computation using landmarks, vectors, planes, and joint-center calculations for mechanical axis and related alignment parameters

- STL-based anatomical visualization for preoperative assessment
- Repeatable algorithmic outputs generated by locked software models and deterministic measurement calculations
- Cloud-hosted processing with GPU-accelerated inference
- Integrated cybersecurity controls for secure system access and data handling

LLAI is designed to segment native lower-limb bony anatomy from CT image data and to identify anatomical landmarks on the resulting bony structures. The device does not segment orthopedic implants as device outputs. Implant-specific subgroup performance was not established as a separate validation endpoint, and performance claims are limited to the evaluated input conditions.

For purposes of the device description and performance characterization, reconstruction parameters refer to CT acquisition and reconstruction characteristics that may influence image appearance and spatial sampling, including slice thickness, through-plane spacing, pixel spacing, reconstruction diameter or field of view, tube voltage, scanner manufacturer/model, and reconstruction kernel where available.

The system is accessed through a secure web interface and does not modify, store, or transmit data beyond the functions required for image processing and clinician review. All measurements and visualizations generated by the device are advisory and are intended to assist, not replace, clinical judgment.

**Indications for Use:**
The AI Planning Logic (AIPL) Lower Limb AI (LLAI) is software intended for use by orthopedic healthcare professionals in the preoperative planning of knee osteotomy procedures. The device processes CT images of the lower limb to provide:

- Automated segmentation and 3D reconstruction of bony anatomy
- Quantitative measurement of lower limb alignment, including mechanical and anatomical axis angles
- Visualization of anatomical structures and surgical planning outcomes in a virtual 3D environment

The software is intended to be used as an adjunctive tool to support clinical judgment and is not intended to provide diagnostic information or to replace the surgeon's decision-making process.

**Technological Characteristics:**
LLAI uses deep-learning segmentation, deterministic geometric algorithms for angle measurement, and a cloud-hosted inference pipeline. The technological characteristics are similar to the predicate devices, which also use automated segmentation, 3D reconstruction, and measurement tools. Differences do not raise new questions of safety or effectiveness.

**Performance Testing – Machine Learning Validation Summary**
Performance testing was conducted to support the substantial equivalence determination for Lower Limb AI (LLAI) and to characterize the performance of the device's machine learning-derived outputs. Testing evaluated segmentation performance, landmark localization, angle measurement, STL representation fidelity, workflow operation, and performance across available imaging conditions and evaluated subgroups. The clinical performance evaluation was retrospective and non-interventional and used de-

identified lower-limb CT image sets. The evaluation assessed device performance and workflow function; patient outcomes, complication rates, and therapeutic benefit were outside the scope of the evaluation.
Training Dataset
Separate segmentation-model training datasets were maintained for the pelvis, knee, and ankle anatomical regions. The pelvis model training dataset included 593 unique patients and 1,280 CT image volumes. The knee model training dataset included 625 unique patients and 1,280 CT image volumes. The ankle model training dataset included 667 unique patients and 1,280 CT image volumes.

A patient could contribute more than one CT volume; therefore, unique-patient counts and CT image-volume counts are reported separately and should not be aggregated across anatomical datasets.

Training images were acquired using CT scanners from multiple manufacturers, including GE, Siemens, Toshiba, and Philips, with smaller contributions from other manufacturers were recorded. The predominant tube voltage was 120 kVp, accounting for approximately 90.70% of the combined training image volumes.
Training-data through-plane spacing and slice-thickness characteristics varied by anatomical model. For the pelvis dataset, through-plane spacing ranged from 0.1 to 10.0 mm and slice thickness ranged from 0.5 to 10.0 mm. For the knee dataset, through-plane spacing ranged from 0.1 to 5.0 mm and slice thickness ranged from 0.5 to 5.0 mm. For the ankle dataset, through-plane spacing ranged from 0.1 to 5.0 mm and slice thickness ranged from 0.3 to 5.0 mm.

Although maximum spacing and slice-thickness values varied by dataset, most training volumes used thinner image spacing. At least 98.2% of training volumes had through-plane spacing of 2.5 mm or less, and at least 99.2% had through-plane spacing of 3.0 mm or less. At least 98.4% of training volumes had slice thickness of 2.5 mm or less, and at least 99.4% had slice thickness of 3.0 mm or less.

Available training metadata indicated approximate age ranges of 11–71 years for the pelvis and knee datasets and 11–75 years for the ankle dataset. Recorded sex/gender information was available at the image-volume-record level. Male-associated image-volume records represented approximately 65% of the pelvis dataset, 65% of the knee dataset, and 68% of the ankle dataset. Female-associated image-volume records represented approximately 33%, 33%, and 30%, respectively. Small proportions were recorded as other, unknown, or anonymized. These distributions do not represent deduplicated unique-patient demographic distributions.

Race and ethnicity were not included in the supplied de-identified training metadata. The Dataset Characterization Report provides the available training-data distributions for tube voltage, pixel spacing, through-plane spacing, reconstruction diameter, scanner manufacturer and model, contributing institutions, collection period, and other available imaging characteristics. Missing or unknown metadata are identified within the applicable tables. The Supplementary Material Supporting Validation Report is identified as the authoritative source for the training dataset patient and CT image-volume counts.

**Validation Dataset**
The clinical performance validation dataset included both internal validation and independent external validation cohorts.

| Validation cohort | Unique patients | Complete image sets |
|---|---|---|
| Internal validation | 170 | 327 |
| Independent external validation | 63 | 116 |

**Demographic Characteristics**
Available demographic information included age and recorded sex/gender at the image-set-record level. Because deduplicated patient-level demographic data were not available for all records, patients contributing multiple image sets may be represented more than once in demographic summaries.

| Cohort | Age information | Recorded sex/gender | Race and ethnicity |
|---|---|---|---|
| Internal validation | Available for 320 of 327 image sets; approximately 17–69 years | Male 230; female 91; other 3; unknown 3 | Not included in supplied de-identified metadata |
| Independent external validation | Available for 101 of 116 image sets; approximately 9–71 years | Male 64; female 45; other 3; unknown 4 | Not included in supplied de-identified metadata |

Race and ethnicity were not included in the supplied de-identified training or validation metadata. The datasets were assembled from retrospective imaging records across multiple acquisition sites, and available metadata were limited to the fields provided by the source datasets, including age, recorded sex/gender, acquisition characteristics, scanner information, and selected imaging parameters. Because race and ethnicity were unavailable, they were not used for subgroup analysis, and no conclusions are made regarding performance across racial or ethnic groups.

**Clinical Subgroups, Confounders, and Edge Cases**
Subgroup analyses were performed according to output type. Segmentation performance was evaluated across tube-voltage and BMI categories. Landmark-localization and angle-measurement performance were evaluated across age, recorded sex/gender, and scanner-manufacturer categories. STL representation performance was evaluated in aggregate because overall accuracy was consistently high and no subgroup-specific performance signal was identified.

No clinically significant subgroup-specific performance patterns were identified among the evaluated subgroups. Several subgroup categories included limited case numbers, and BMI information was unavailable for a substantial proportion of datasets. Accordingly, the subgroup analyses support performance characterization for the evaluated data but do not establish equivalent performance across all patient populations or acquisition conditions.

Reviewed edge cases included incomplete or zoomed anatomy, ankle-tip holes, unusual or distorted anatomy, and connected femur or tibia. Cases outside intended input conditions were excluded from applicable quantitative landmark and angle analyses and were separately reviewed for potential safety impact.

**Implants and Reconstruction Parameters**
LLAI does not segment orthopedic implants as device outputs. The segmentation and landmark-localization algorithms are intended to identify native bony anatomy for lower-limb preoperative planning. Implant-specific subgroup performance was not established as a separate validation endpoint. As a result, performance claims are limited to the evaluated input conditions, and the 510(k) Summary and labeling do not claim validated robustness across implants.

For the device description and performance discussion, “reconstruction parameters” refer to CT acquisition and reconstruction characteristics that may influence image appearance and spatial sampling, including slice thickness, through-plane spacing, pixel spacing, reconstruction diameter or field of view, tube voltage, scanner manufacturer/model, and reconstruction kernel where available. Performance claims are limited to the patient populations, acquisition conditions, reconstruction characteristics, and input-quality characteristics represented in the training and validation datasets.

**Imaging Equipment and Acquisition Characteristics**
Validation datasets were collected from multiple clinical acquisition sites and included CT scanners from multiple manufacturers. Internal-validation image sets were acquired using scanners from GE Medical Systems, Siemens, Toshiba, Philips, and Canon Medical Systems. Independent external-validation image sets were acquired using recorded scanner models from GE Medical Systems, Philips, Siemens Healthineers, Siemens, and Toshiba.

Most validation image sets were acquired at 120 kVp. Across the internal and independent external cohorts, excluding two internal image sets with missing or invalid tube-voltage metadata, 400 of 441 image sets, or 90.70%, were acquired at 120 kVp.

For internal validation, both through-plane spacing and slice thickness ranged from 0.3 to 2.5 mm. For independent external validation, both ranged from 0.4 to 2.5 mm. Available metadata also characterized pixel spacing, reconstruction diameter, scanner manufacturers and models, acquisition sites, and other imaging characteristics.

**Reference Standard and Truthing Process**
Segmentation reference masks were generated through manual annotation in ITK-SNAP. Trained annotators edited and refined the masks to remove irrelevant anatomical structures and establish anatomically appropriate segmentation boundaries. Expert clinicians reviewed the resulting masks for anatomical correctness and clinical validity but did not directly edit them. Any discrepancies identified during clinical review were returned to the trained annotators for correction and subsequent re-review before acceptance.

Qualified clinical experts established fixed reference-standard landmark coordinates using 3D CAD software tools. Joint angles were calculated from those landmarks using independently verified angle-computation software. Reference-standard data were locked before comparison with AI outputs.

Independent external validation used triangulated comparison among AI Core outputs, a separate expert orthopedic surgeon assessment, and the 3D CAD software tools derived reference standard. When disagreement exceeded protocol-defined tolerance, additional expert review, consensus, or adjudication was required before final disposition.

**Independence of Test Data from Training Data**
The production software and model versions were frozen, and validation datasets were locked before validation testing. No patient, CT image volume, CT series, reconstructed volume, derived image, segmentation mask, landmark annotation, or other data from the 116-case independent external validation dataset were used for model training, model selection, checkpoint selection, hyperparameter tuning, operating-threshold selection, acceptance-criterion development, or adaptation of the released models.

De-identified patient identifiers, image-set identifiers, site records, and controlled dataset inventories were reviewed to maintain separation between development data and independent external test data. No retraining or model modification was performed in response to validation results.

**Performance Testing Results**
LLAI met the prespecified acceptance criteria for the evaluated outputs.

| **Output** | **Test method** | **Acceptance criteria / evaluation framework** | **Results** |
|---|---|---|---|
| Segmentation | Comparison with expert-verified reference masks using Dice, Intersection over Union, HD95, precision, and recall | Dice ≥ 0.95; IoU ≥ 0.90; HD95 ≤ 3.5 mm; precision ≥ 0.90; recall ≥ 0.90 | All endpoints passed. Mean Dice values ranged from approximately 0.9916 to 0.9965 across anatomical regions and validation cohorts. Mean HD95 values were below 1 mm. |
| Landmark localization | Three-dimensional radial distance between AI-generated, reference-standard, and expert landmarks | Overall mean radial error ≤ 7 mm; standard deviation ≤ 5 mm; deviations clinically reviewed; no unresolved safety concern | All landmark-localization comparisons passed. Mean radial error values ranged from approximately 3.611 mm to 4.213 mm across reported comparison groups. |
| Angle measurement | Mean absolute error, signed bias, standard deviation, interquartile range, confidence intervals, Bland–Altman analysis, expert-comparator agreement, outlier review, and residual-risk assessment | Protocol-defined agreement framework; deterministic computation verified; deviations clinically reviewed; no unresolved safety concern | Angle validation passed. Greater variability was observed for geometrically sensitive measurements, and users are instructed to review and, where necessary, correct underlying landmarks before relying on derived measurements. |
| STL representation | Hausdorff distance, average surface distance, volume ratio, mesh-integrity review, and clinical-acceptability review | HD ≤ 2.5 mm; ASD ≤ 0.5 mm; volume ratio ≥ 0.95; valid mesh; clinically acceptable | STL representation met prespecified acceptance criteria, supporting high-fidelity surface reconstruction relative to reference representations. |

The validation evidence demonstrates that LLAI performs as intended for the evaluated lower-limb CT imaging conditions and met the prespecified acceptance criteria for segmentation, landmark localization, angle-measurement evaluation, and STL representation. The results support the device's performance for its intended use while recognizing limitations in available validation metadata and evaluated subgroups, including unavailable race/ethnicity data, incomplete BMI data, and lack of implant-specific subgroup validation.

**Substantial Equivalence:**

The Indications for Use of the subject device and the predicate devices are similar. Differences do not constitute a different intended use because all devices are intended to provide 3D models, measurements, and pre-surgical planning information generated from CT input for orthopedic healthcare professionals.

The subject and predicate devices have similar technological characteristics. Differences in output format and user interface do not introduce new questions of safety or effectiveness.

Performance testing demonstrates that the subject device performs as intended and meets its predefined acceptance criteria. Prospective clinical outcome data were not required to support the substantial equivalence determination.

| **Category** | **Subject Device (LLAI)** | **Primary Predicate (K240642 – SMART Bun-Yo-Matic CT)** | **Reference Predicate (K252856 – PeekMed Web)** |
|---|---|---|---|
| Manufacturer | AI Planning Logic, Inc. | Disior Ltd | PeekMed |
| Trade Name | Lower Limb AI (LLAI) | SMART Bun-Yo-Matic CT | PeekMed Web |
| Input | CT imaging (DICOM) of the lower limb | CT imaging (DICOM) | CT imaging (DICOM) |
| Image Processing | Automated segmentation of bone structures; anatomical landmark detection; 3D reconstruction; quantitative alignment measurements | Automated segmentation of bone structures; 3D reconstruction; case report generation | Automated segmentation, 3D reconstruction, and orthopedic planning tools |
| Output | Segmented bone models, anatomical landmarks, 3D reconstructions, quantitative alignment measurements for pre-operative planning | 3D model of patient anatomy; surgical instrument parameters; case report | 3D models, measurements, and planning tools for orthopedic assessment |
| Measuring & Planning | Deterministic geometric algorithms for angle and alignment measurement; supports orthopedic pre-operative planning | Performs measurements for presurgical planning | Performs measurements and planning for orthopedic procedures |
| User Interface | Web-based graphical user interface accessed through a standard browser | Standalone application-based GUI | Web-based GUI |
| Technological Characteristics | Deep-learning segmentation ; cloud-hosted inference pipeline; deterministic measurement algorithms | Automated segmentation and measurement algorithms; workstation-based processing | Automated segmentation and measurement algorithms; cloud-enabled workflow |
| Performance Testing | Validation testing evaluated internal and independent external CT image sets. LLAI met prespecified acceptance criteria for segmentation, landmark localization, angle- | Predicate meets acceptance criteria of 95% model conformance within 1.0 mm and 2° SD | Predicate demonstrates acceptable segmentation and |

| | | | |
|---|---|---|---|
| | measurement evaluation, STL representation, and workflow performance under the evaluated imaging conditions. Mean Dice values ranged from approximately 0.9916 to 0.9965, and mean HD95 values were below 1 mm. Performance claims are limited to conditions represented in the validation datasets, and implant-specific subgroup performance was not established. | for angular measurements | measurement accuracy |

**Safety and Clinical Interpretation:**
No clinically unsafe systematic output or unresolved device-related safety concern was identified during validation. The evaluations were retrospective and non-interventional and were not designed to demonstrate improved patient outcomes or reduced complication rates. Device outputs remain advisory and must be reviewed by qualified users before use in planning.

**Conclusion:**
LLAI has the same intended use and similar technological characteristics as the predicate devices. Differences in technological characteristics do not raise new questions of safety or effectiveness. Under the evaluated conditions, performance testing demonstrated that LLAI performs as intended and meets its predefined acceptance criteria. Based on the intended use, technological characteristics, and performance testing, LLAI is substantially equivalent to the predicate and reference devices.