Longwood Valley Medical Ltd
Wei Yuanyuan
RA Manager
2201 Floor 22, Tower 1, No.2 Ronghua South Rd.,
BDA 100176 Beijing, China

August 5, 2024

Re: K233761
Trade/Device Name: Orthopaedic Surgery Planning Software (AIJOINT)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: July 1, 2024
Received: July 1, 2024

Dear Wei Yuanyuan :

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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)*

K233761

Device Name

Orthopaedic Surgery Planning Software (AIJOINT)

Indications for Use *(Describe)*

This product is used in medical institutions, it can carry out 3D reconstruction, segmentation and semi-automatic identification of key points on CT images conforming to DICOM3.0 standard format, and assist physicians to overlay digital templates to assist surgeons with preoperative planning of adult hip and total knee replacement surgery. This product is intended for use by trained and qualified physicians and cannot be used as a basis for clinical diagnosis and treatment decisions alone.

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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K233761-510(k) Summary

Date of Preparation: 7/31/2024

1. Sponsor Identification

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2. Designated Submission Correspondent

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3. Identification of Proposed Device

Trade Name: Orthopaedic Surgery Planning Software (AIJOINT)
Common Name: Pre-operative planning software

Regulatory Information
Regulation Name: Medical image management and processing system
Classification: Class II
Product Code: LLZ
Regulation Number: 21 CFR 892.2050
Review Panel: Radiology

Indication for Use:
This product is used in medical institutions, it can carry out 3D reconstruction, segmentation and semi-automatic identification of key points on CT images conforming to DICOM3.0 standard format, and assist physicians to overlay digital templates to assist surgeons with preoperative planning of adult hip and total knee replacement surgery. This product is intended for use by trained and qualified physicians and cannot be used as a basis for clinical diagnosis and treatment decisions alone.

4. Identification of Predicate Devices

510(k) Number: K182464
Product Name: PeekMed

Indications for Use:
PeekMed is a software system designed to help surgeons' specialists carry out the pre-operative planning in a prompt and efficient manner for several surgical procedures, based on their patients' imaging studies.
The software imports diagnostics imaging studies such as x-rays, CT or magnetic resonance image (MRI). The import process can retrieve files from a CD ROM, a local folder or the PACS. In parallel, there is a database of digital representations related to prosthetic materials supplied by their producing companies.
PeekMed allows health professional to digitally perform the surgical planning without adding any additional steps to that process. This software system requires no imaging study acquisition specification (no protocol). Experience in usage and a clinical assessment are necessary for a proper use of the software.

5. Device Description

The proposed device, Orthopaedic Surgery Planning Software, is standalone software which is designed to help surgeons' specialists carry out the pre-operative planning for an adult hip and total

knee replacement surgery for several surgical procedures, based on the patient's CT images.

The Orthopaedic Surgery Planning Software can a carry out 3D reconstruction, segmentation and semi-automated identification of anatomical sites of CT images conforming to DICOM3.0 standard format, and assist physicians to simulate adult hip and total knee replacement surgery.

6. Substantially Equivalent (SE) Comparison

Table 1 Technical Characteristics Comparison

ITEM	Proposed Device	Predicate Device K182464	Remark
Product name	Orthopaedic Surgery Planning Software	PeekMed	/
Regulation No.	21 CFR 892.2050	21 CFR 892.2050	Same
Product Code	LLZ	LLZ	Same
Class	II	II	Same
Intended for Use	A pre-operative planning software for surgery	A pre-operative planning software for surgery	Same
Indication for Use	This product is used in medical institutions, it can carry out 3D reconstruction, segmentation and semi-automatic identification of key points on CT images conforming to DICOM3.0 standard format, and assist physicians to overlay digital templates to assist surgeons with preoperative planning of adult hip and total knee replacement surgery. This product is intended for use by trained and qualified physicians and cannot be used as a basis for clinical diagnosis and treatment decisions	PeekMed is a software system designed to help surgeons' specialists carry out the pre-operative planning in a prompt and efficient manner for several surgical procedures, based on their patients' imaging studies. The software imports diagnostics imaging studies such as x-rays, CT or magnetic resonance image (MRI). The import process can retrieve files from a CD ROM, a local folder or the PACS. In parallel, there is a database of digital representations related to prosthetic materials supplied by their producing companies. PeekMed allows health professional to digitally perform the surgical planning without adding any additional steps to	Similar Analysis 1

	alone.	that process. This software system requires no imaging study acquisition specification (no protocol). Experience in usage and a clinical assessment are necessary for a proper use of the software.	
Subspecialties	AIJOINT allows the surgeon to perform the pre-surgical planning efficiently in the following subspecialties: - Hip - Knee	PeekMed allows the surgeon to perform the pre-surgical planning efficiently in the following subspecialties: - Hip - Knee - Spine - Upper Limb - Foot and Ankle - Trauma	Different Analysis 2
	For each subspecialty, there are several procedures: -Hip: Hip Dysplasia Correction, Limb Length Discrepancy, Acetabular Angle, Hip Arthroplasty	For each subspecialty, there are several procedures: -Hip: Hip Dysplasia Correction, Limb Length Discrepancy, Center of Rotation – Ranawat method, Acetabular Angle, Total Hip Arthroplasty	
	-Knee: Knee Arthroplasty	-Knee: Leg Deformity Correction, AP Knee Resection, AP Full Leg resection, High Tibial Osteotomy, ACL Tunnel Reconstruction, Medial Patellofemoral Ligament	
	/	-Spine: Single Cobb Angle, Thoracic Kyphosis Angle, Lumbar Lordosis Angle, Sagittal Vertical Axis, Pelvic Angles, Coronal Balance, Sacro- femoral Angle, Sagittal Balance, Smith-Petersen	

		Osteotomy, Pedicle Subtraction Osteotomy	
	/	-Upper Limb: Total Shoulder Replacement, Clavicular Angle, Shoulder Resurfacing	
	/	-Foot and Ankle: Talar Tilt, Hallux Valgus, Moreau-Costa-Bertani Internal Angle, Moreau- Costa-Bertani External Angle, Maestro Formula	
	/	-Trauma: Diaphyseal Shaft Fracture Angle, Metaphyseal Shaft Fracture Angle, Roof Arc	
Patient Population	Adults	Adults and pediatrics	Different Analysis 3
End Users	Surgeons	Surgeons	Same
Computer	Personal Computer	Personal Computer or Workstation	Same
Operating System	Windows	Windows or OS X	Different Analysis 4
Device Availability	It can be set to start from a computer standalone for planning procedures	It can be set to start from a workstation or standalone for planning procedures	Same
Images Source	Receives medical images from computer local client end.	Receives medical images from various sources (including PACS)	Same
Data Processing	The software processes data in order to provide an overlap and dimensioning of digital representations of the prosthetic material	The software processes data in order to provide an overlap and dimensioning of digital representations of the prosthetic material	Same

Digital Overlap of Prosthetic Material	Allows the overlap of models and the intersection of the models	Allows the overlap of models and the intersection of the models	Same
Interactive Model Positioning	Yes	Yes	Same
Interactive Model Dimensioning	Yes	Yes	Same
Model Rotation	Yes	Yes	Same
Support for Digital Prosthetic Materials Provided by the Manufacturers	Yes	Yes	Same
Automatic Calibration	Yes	Yes	Same
Pre-surgical Planning	Yes	Yes	Same
Contact with the Patient	No	No	Same
Control of life Supporting Devices	No	No	Same
Human Intervention for Image Interpretation	Yes	Yes	Same

Similar Analysis 1- Indication for Use

Both the proposed device and predicate device are the pre-operative planning software for surgery. Both the proposed device and predicate device have a database of digital representations related to prosthetic materials supplied by their producing companies.

The image source for the proposed device is CT, the image source for the predicate device is CT, x-rays and MRI. The image source for the proposed device is within the scope of the image sources for the predicate device.

The import process for the proposed device can retrieve files from a local folder; The import process for the predicate device can retrieve files from a CD ROM, a local folder or the PACS. The import process for the proposed device is within the scope of the import process for the predicate device.

Based on above analysis, the indication for use of the proposed device is within the scope of the indication for use of the predicate device.

Different Analysis 2- Subspecialties

The Subspecialties of the proposed device and the predicate device is different. The proposed device and predicate device are all applicable to the Hip and Knee procedures, although they are applicable to different detail hip/knee procedure, the software verification and validation testing and performance testing demonstrate that the proposed device's safety and effectiveness.

Different Analysis 3- Patient Population

The patient population of the proposed device and the predicate device is different. The users use the proposed device for adult patients according to the indications for use that the difference will not affect the safety and effectiveness of the proposed device.

Different Analysis 4- Operating System

The type of operating system of proposed device is within the types of the predicate device. The difference will not affect the safety and effectiveness of the proposed device.

7. Non-Clinical Test Conclusion

Internal verification and validation testing were conducted to verify that the proposed device met all design requirements and was Substantially Equivalent (SE) to the predicate devices.

Validation activities for the proposed device consisted of:

- The accuracy testing of key point recognition, comparing with the key points identified annotated by professional physicians for precision. Testing shows that key point coordinates have actual error distance is below 1mm. Bland-Altman plots show that all points are within the 95% CI.
- The accuracy testing of image segmentation, comparing with the segmentation results of the mature software available in the market. Testing shows that the mean Dice coefficient and the mean Hausdorff Distance of 200 patient cases (100 cases per region) were 0.9483 and 1.2917.
- The accuracy verification of the output parameters from the proposed device. Testing shows that the accuracy of the output parameters of the orthopedic surgery planning software is within the length measurement accuracy of 1mm and the Angle measurement accuracy of 1°.
- The verification on the consistency of prosthesis model data. Comparing the self-drawn prosthesis model data and the real prosthesis model data provided by the manufacturer, the deviations are all below 0.5mm.
- The accuracy verification of the output acetabular cup coverage. Testing shows that the accuracy of the output acetabular cup coverage of the orthopedic surgery planning software is within ±3%.

Software verification and validation were performed, and documentation was provided following the FDA guidance "Content of Premarket Submissions for Device Software Functions." This includes verification against defined requirements, and validation against user needs.

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as

effective, and performs as well as the legally marketed predicate devices.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the subject device is substantially equivalent to the legally marketed predicate device, K182464.