August 28, 2025

Twinsight
Meghan McFadden
Quality and Regulatory Affairs Engineer
Biopolis
5 avenue du Grand Sablon
La Tronche, 38700
France

Re: K250290
Trade/Device Name: SurgiTwin
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ, QIH
Dated: January 31, 2025
Received: January 31, 2025

Dear Meghan McFadden:

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.

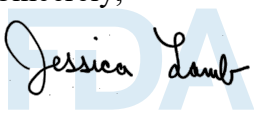
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier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



Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic Imaging
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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)*

K250290

Device Name

SurgiTwin

Indications for Use *(Describe)*

SurgiTwin is a web-based platform designed to help healthcare professionals carry out pre-operative planning for knee reconstruction procedures, based on their patients' imported imaging studies. Experience in usage and a clinical assessment is necessary for the proper use of the system in the revision and approval of the output of the planning.

The system works with a database of digital representations related to surgical materials supplied by their manufacturers. SurgiTwin generates a PDF report as an output. End users of the generated SurgiTwin reports are trained healthcare professionals. SurgiTwin does not provide a diagnosis or surgical recommendation.

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

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter

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France

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Date Summary Prepared: 29 August, 2025

2. Device

2.1. SurgiTwin

Trade Name/Common Name:	SurgiTwin
Classification Name:	Medical image management and processing system (21 C.F.R. § 892.2050)
Regulatory Class:	Class II
Product Code:	LLZ, QIH
510(k) Number:	K250290

3. Legally Marketed Predicate Device

3.1. Peekmed web

510(k)	Product Name	Clearance Date
K240926	PeekMed web	December 2024

4. Device Description Summary

SurgiTwin is a semi-automated Software as a Medical Device (SaMD) that assists health care professionals in the pre-operative planning of total knee replacement surgery. Using a series of algorithms, the software creates 2D segmented images, a 3D model, and relevant measurements derived from the patient's pre-dimensioned medical images. The software interface allows the user to adjust the plan manually to verify the accuracy of the model and achieve the desired clinical targets. SurgiTwin generates a PDF report as an output. SurgiTwin does not provide a diagnosis or surgical recommendation.

The intended patient population is patients over 22 undergoing total knee replacement surgery without any existing material in the operated lower limb.

5. Intended Use/Indications for Use

SurgiTwin is a web-based platform designed to help healthcare professionals carry out pre-operative planning for knee reconstruction procedures, based on their patients' imported imaging studies. Experience in usage and a clinical assessment is necessary for the proper use of the system in the revision and approval of the output of the planning.

The system works with a database of digital representations related to surgical materials supplied by their manufacturers. SurgiTwin generates a PDF report as an output. End users of the generated SurgiTwin reports are trained healthcare professionals. SurgiTwin does not provide a diagnosis or surgical recommendation.

5.1. Contraindications

SurgiTwin is contraindicated as follows:

1. Patients under 22 years of age
2. Presence of orthopedic hardware in the limb to be operated
3. Pathological anomaly in the limb to be operated including fracture, tumor, or significant bone loss
4. Patients with severe limb deformities
5. Contraindications for each implant as indicated by the implant manufacturer

5.2. Indications for Use Comparison

SurgiTwin assists the surgeon in pre-surgical planning of the knee, while the predicate allows planning in the knee, hip, upper limb, and foot. The anatomical region and surgical procedure covered in SurgiTwin are included in its predicate. Comparison of the indications for use therefore supports the substantial equivalence of SurgiTwin and its predicate.

6. Technological Comparison to Predicate

SurgiTwin has been evaluated in comparison to its predicate device regarding intended use, indications for use, design, function, and technology. Both the subject device and its predicate are medical software designed to assist healthcare professionals in orthopedic pre-surgical planning for the adult musculoskeletal system within a clinical setting. Appropriate clinical judgment and experience are mandatory for the use of both devices.

The two devices follow the same workflow, share similar use requirements (such as internet connectivity and user verification and approval of outputs), and offer comparable planning functionalities, including model representation, digital overlap of prosthetic material, and support for both 2D and 3D environments. Additionally, both devices generate a final planning report that incorporates selected images with templates, measurements, and textual descriptions of the patient and/or the planned surgical procedure.

The analysis of technological differences between SurgiTwin and the predicate device performed in the context of this 510(k) submission supports substantial equivalence. A summary of this comparison is presented in the table below.

Table 1: Summary of predicate and subject device characteristics and rationale for substantial equivalence

Characteristic	Peekmed web K240926	SurgiTwin Subject Device K250290	Substantially Equivalent?	Justification and rationale
Product Code	LLZ, QIH	LLZ, QIH	Yes	–
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Yes	–
Regulation Name	Medical Image Management And Processing System	Medical Image Management And Processing System	Yes	–
Intended Use	PeekMed web is a system designed to help healthcare professionals carry out pre-operative planning for several surgical procedures, based on their imported patients' imaging studies. Experience in usage and a clinical assessment is necessary for the proper use of the system in the revision and approval of the output of the planning. The multi-platform system works with a database of digital representations related to surgical materials supplied by their manufacturers.	SurgiTwin is a web-based platform designed to help healthcare professionals carry out pre-operative planning for knee reconstruction procedures, based on their patients' imported imaging studies. Experience in usage and a clinical assessment is necessary for the proper use of the system in the revision and approval of the output of the planning. The system works with a database of digital representations related to surgical materials supplied by their manufacturers. SurgiTwin generates a PDF report as an output. End users of the generated SurgiTwin reports are trained healthcare professionals. SurgiTwin does not provide a diagnosis or surgical recommendation.	**Yes** See justification	The last three sentences have been added for clarification but do not alter the intended use compared to the predicate.

Characteristic	Peekmed web K240926	SurgiTwin Subject Device K250290	Substantially Equivalent?	Justification and rationale
Indications for Use	This medical device consists of a decision support tool for qualified healthcare professionals to quickly and efficiently perform the pre-operative planning for several surgical procedures, using medical imaging with the additional capability of planning the 2D or 3D environment. The system is designed for the medical specialties within surgery and no specific use environment is mandatory, whereas the typical use environment is a room with a computer. The patient target group is adult patients who have an injury or disability diagnosed previously. There are no other considerations for the intended patient population.	This medical device consists of a decision support tool for qualified healthcare professionals to quickly and efficiently perform the pre-operative planning for total knee arthroplasty procedures, using medical imaging with the additional capability of planning the 2D or 3D environment. The system is designed for medical specialties within surgery and no specific use environment is mandatory. The typical use environment is a room with a computer. The intended patient group is patients over 22 years old identified to require knee reconstruction surgery without any existing material in the operated lower limb.	**Yes** See justification	SurgiTwin allows the surgeon to perform the pre-surgical planning efficiently in the knee, while the predicate allows planning in the hip, knee, upper limb, and foot. The anatomical region and surgical procedure covered in SurgiTwin are included in its predicate. Comparison of the indications for use therefore supports substantial equivalence.

Characteristic	Peekmed web K240926	SurgiTwin Subject Device K250290	Substantially Equivalent?	Justification and rationale
Contraindications	No contraindications specific to this device.	SurgiTwin is contraindicated as follows: - Patients under 22 years of age - Presence of orthopedic hardware in the joint to be operated - Pathological anomaly in the limb to be operated including fracture, tumor, or significant bone loss - Patients with severe limb deformities - Contraindications for each implant as given by the implant manufacturer	**Yes** See justification	Contraindications are added as a precautionary measure to enhance user awareness and ensure safe and appropriate use of the device within its intended population. They do not indicate a fundamental difference in SurgiTwin's technological characteristics, intended use, or performance compared to the predicate.
Clinical Purpose	PeekMed web allows the surgeon to efficiently perform orthopedic pre-surgical planning in the musculoskeletal system	SurgiTwin allows the surgeon to efficiently perform orthopedic pre-surgical planning in the knee	**Yes** See justification	SurgiTwin allows the surgeon to perform the pre-surgical planning efficiently in the knee, while PeekMed® web allows planning in the hip, knee, upper limb, and foot. The anatomical region and surgical procedure covered in SurgiTwin are included in its predicate. Comparison of the general purpose therefore supports substantial equivalence.
Anatomical Regions	PeekMed web allows the surgeon to perform the pre-surgical planning in the following anatomical regions: - Hip - Knee - Upper limb - Foot	SurgiTwin allows the surgeon to efficiently perform orthopedic pre-surgical planning in the knee	**Yes** See justification	See justification above.

Characteristic	Peekmed web K240926	SurgiTwin Subject Device K250290	Substantially Equivalent?	Justification and rationale
Patient Population	Adults	Adults	Yes	
End Users	Healthcare Professionals	Healthcare Professionals	Yes	–
Device Availability	Software is cloud-based (not installable) and can be displayed on any personal device or workstation that can run on a web browser	Software is cloud-based (not installable) and can be displayed on any personal device or workstation that can run on a web browser	Yes	–
Software Architecture	Distributed system (cloud-based). This distributed system is a combination of software modules placed on servers that are able to communicate with each other.	Distributed system (cloud-based). This distributed system is a combination of software modules placed on servers that are able to communicate with each other.	Yes	–
Workflow	The workflow is as follows: Import case images, configure images, identify the case, pre-surgical planning, and export the case.	The workflow is as follows: Import case images, configure images, identify the case, pre-surgical planning, and export the case.	Yes	–
Internet Connection	Required	Required	Yes	
Image Source	Receives medical images from various sources	Receives medical images from various sources	Yes	–
Data Processing	The software processes data to provide an overlap and dimensioning of digital representations of the prosthetic material	The software processes data to provide an overlap and dimensioning of digital representations of the prosthetic material	Yes	–
Digital overlap of templates	Allows the overlap of models and the intersection of the models	Allows the overlap of models and the intersection of the models	Yes	–
Interactive model positioning	Yes	Yes	Yes	–

Characteristic	Peekmed web K240926	SurgiTwin Subject Device K250290	Substantially Equivalent?	Justification and rationale
Interactive model dimensioning	Yes	Yes	Yes	–
Model Rotation	Yes	Yes	Yes	–
Support for digital prosthetic materials provided by the manufacturers	Yes	Yes	Yes	–
Contact with the patient	No	No	Yes	–
Control of life supporting devices	No	No	Yes	–
Human intervention for image interpretation	Yes	Yes	Yes	–
Tools for surgical simulation and planning	Yes	Yes	Yes	–
Preoperative annotation and analysis	Yes	Yes	Yes	–
Provides values for measurement	Yes, including distance and angle measurement	Yes, including distance and angle measurement	Yes	–
Automatic bone segmentation	Yes	Yes	Yes	–
Machine learning models for image segmentation	Yes	Yes	Yes	–

Characteristic	Peekmed web K240926	SurgiTwin Subject Device K250290	Substantially Equivalent?	Justification and rationale
MPR View	Yes	Yes	Yes	–
Automatic placement of anatomical landmarks	Yes	Yes	Yes	–
Approval of anatomical landmarks by user	Yes	Yes		-
Modification of anatomical landmarks	Yes	No	**Yes** See justification	See discussion of technological differences below.

6.1. Discussion of Technological Differences

The device and its predicate have the following differences:

1. SurgiTwin supports automatic landmark placement while PeekMed web supports both manual and automatic landmark placement. Landmark placement is required to be validated by the qualified orthopedic surgeon using the software in order to generate the planning results.
2. SurgiTwin allows the surgeon to perform the pre-surgical planning in the knee, while PeekMed® web allows planning in the hip, knee, upper limb, and foot.

The assessment of these technological differences supports substantial equivalence of SurgiTwin to its predicate because:

1. The automatic landmarking feature is designed to streamline the placement of landmarks on each bone before surgical planning, but is not intended to provide medical advice on their positioning. The qualified user must review and validate the landmark placement before proceeding with surgical planning. In addition, performance testing and validation confirmed that the automatic landmarking feature is more accurate than that of the predicate. The requirement for user approval ensures that clinicians review landmark placement before continuing.
2. The anatomical region and surgical procedure covered in SurgiTwin are included in its predicate.

7. Performance Data

Nonclinical performance testing performed on SurgiTwin supports substantial equivalence to the predicate device. Testing was performed in accordance with the following FDA guidance documents:

- Content of Premarket Submissions for Device Software Functions
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
- Applying Human Factors and Usability Engineering to Medical Devices
- Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions
- Off-The-Shelf Software Use in Medical Devices

The following testing was performed:

A. Verification activities to ensure that all features were correctly implemented to meet system requirements and fulfill acceptance criteria.
B. The machine learning (ML) model incorporated into SurgiTwin was developed, trained, tested, and validated for its performance.
    a. **ML Model Development and Testing Information**

ML models were developed with datasets from multiple sites. The ML model was trained with 81% of the dataset and tested with the remaining 19%. This dataset was designed to represent the intended use population.

b. **Subgroup Definition**

Datasets were divided according to the following subgroups:

- Demographics
  - Patient Sex
  - Patient Age
- Equipment and protocols for image collection
  - Institution Name
  - Institution Location
  - Manufacturer
  - Image slice thickness

The CT image parameters in the final test dataset fall within the acceptable input specifications for the SurgiTwin system:

- 0.3 mm to 5 mm pixel spacing and slice interval for hip-only and ankle-only scans
- 0.3 mm to 1.0 mm for scans including the knee region

c. **Acceptance Criteria**

The acceptance criteria for the segmentation ML model are shown in the following table:

Metric	Acceptance Criteria
Mean DSC	> 0.95
Mean voxel based AHD	< 1.0mm
5th percentile of the DSC	> 0.9
95th percentile of the boundary based HD 95	< 2.5mm

d. **Reference Standard**

Comparison of the performance of the segmentation ML model against the predefined ground truth met the acceptance criteria for the model performance.

e. **Independence of Training and Validation Data**

To prevent data leakage, external validation datasets were collected separately from the development data. The validation dataset was labeled by different individuals

from the training dataset.

The results from testing confirm that the ML model demonstrates acceptable performance for its intended population.

C. The automatic landmark function was validated using a study to compare automatic landmarking performance to manual landmark placement by expert annotators. The system met predefined clinical acceptance criteria.

D. A validation study was conducted to compare metrics generated by SurgiTwin to those from manual annotations by expert annotators. The system met predefined clinical acceptance criteria for all measurements.

E. A validation study was performed to confirm the accuracy and clinical acceptability of the default implant placement algorithm. All acceptance criteria were met.

F. A validation study was performed to verify the clinical acceptability of the osteophyte removal function. All acceptance criteria were met.

G. External validation tests were performed by qualified personnel in an environment simulating the real end-user environment using a pre-defined test protocol. All acceptance criteria were met.

Nonclinical performance testing demonstrated that the subject device fulfills its intended use with an acceptable performance according to clinical acceptance criteria for all functions. These tests will be repeated and updated when appropriate to ensure that the software continues to meet performance criteria. Performance testing of SurgiTwin therefore supports substantial equivalence to its predicate.

8. Conclusion

Based on the information presented in this 510(k) submission, SurgiTwin has been determined to be substantially equivalent to the legally marketed predicate device in terms of indications for use, intended use, design, technology, and performance.