July 15, 2026

UPlanner B.V. | Presurgeo
% Carrie Britton
Founder and CEO
Britton Medical Consultancy, LLC
19123 W. 60th Lane
Golden, Colorado 80403

Re: K260206
Trade/Device Name: SkeletonPlanner
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: June 12, 2026
Received: June 15, 2026

Dear Carrie Britton:

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K260206

Device Name
SkeletonPlanner

Indications for Use *(Describe)*
SkeletonPlanner is intended to assist radiologists and orthopedic surgeons in the analysis of lower extremity alignment and/or preoperative planning of skeletal surgery procedures. It supports assessment of bone deformities in the femur and tibia and plan corrections for deformities amenable to single femoral or tibial osteotomies for skeletally mature patients 18 years of age and older.

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.

510(k) Summary
SkeletonPlanner
K260206

1. **Submission Sponsor**

Uplanner B.V. | PRESURGEO

Nigtevechtseweg 94

3633 XW VREELAND

The Netherlands

Contact: Jessica Adams

Title: CEO

2. **Submission Correspondent**

Britton Medical Consultancy LLC

19123 60th Lane

Golden, CO 80403

Office Phone: (720) 838-4113

Contact: Carrie Britton

Title: Founder and CEO

Date Prepared

July 14th, 2026

3. **Device Identification** *(per 21 CFR 807.92(a)(2))*

Proprietary Name	SkeletonPlanner
Common / Usual Name	Orthopedic surgical planning software
Classification Name	Orthopedic stereotaxic planning software
Regulation Number	21 CFR 892.2050
Regulation Name	Medical image management and processing system
Product Code	QIH
Device Class	II
Classification Panel	Radiology

4. **Legally Marketed Predicate Device(s)** *(per 21 CFR 807.92(a)(3))*

The subject device SkeletonPlanner claims substantial equivalence to the following legally marketed predicate device:

Trade Name	SurgiCase Viewer
Manufacturer	Materialise NV
510(k) Number	K213684
Regulation Number	21 CFR 892.2050
Regulation Name	Medical image management and processing system
Product Code	LLZ
Device Class	II

The predicate device has not been withdrawn, removed, or found adulterated or misbranded by FDA.

5. **Indication for Use Statement** *(per 21 CFR 807.92(a)(5))*

SkeletonPlanner is intended to assist radiologists and orthopedic surgeons in the analysis of lower extremity alignment and/or preoperative planning of skeletal surgery procedures. It supports assessment of bone deformities in the femur and tibia and plan corrections for deformities amenable to single femoral or tibial osteotomies for skeletally mature patients 18 years of age and older.

6. **Device Description** *(per 21 CFR 807.92(a)(4))*

SkeletonPlanner is a semi-automated, cloud-based Software as a Medical Device (SaMD) accessed through standard web browsers. The system accepts CT DICOM data of the lower limbs, reconstructs 3D bone models using a deep learning segmentation component (nnU-Net), identifies anatomical landmarks, calculates alignment angles, and generates semi-automated osteotomy planning recommendations. All outputs require review and confirmation by a qualified clinician.

Outputs include 3D visualizations, tabular measurements, customizable osteotomy plans, printable reports, and case notes. The user interface consists of a web-based GUI with tabbed navigation and an interactive 3D viewer. The device is intended for use by licensed radiologists and orthopedic surgeons in hospital or clinical environments. No proprietary hardware, implants, drugs, or patient-contacting materials are included.

7. **Substantial Equivalence** *(per 21 CFR 807.92(a)(6))*

A comparison of technological characteristics between SkeletonPlanner and the predicate SurgiCase Viewer (K213684) is provided below.

Key points:

- Both devices are regulated under **21 CFR 892.2050**, Class II.
- Both are **SaMD** intended for orthopedic visualization and preoperative planning.
- Both share the same intended users and patient population.

- Differences in deployment (cloud-based vs. desktop), automation level, and product code (QIH vs. LLZ) do not alter the intended use and do not raise new questions of safety or effectiveness.

Table 1. Substantial Equivalence Table

Feature / Characteristic	SkeletonPlanner (Presurgeo)	Predicate – SurgiCase Viewer (K213684)	Comparison / Notes
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	**Same**
Regulatory Class	II	II	**Same**
Product Code	QIH	LLZ	Different codes; both under 21 CFR 892.2050 — reflects FDA classification refinement; does not alter intended use
Device Type	SaMD	SaMD	**Same**
Platform	Cloud-based, web browser	Desktop software	Different deployment; both operate on standard computing hardware; does not raise new safety/effectiveness questions
Input Data	CT DICOM data of lower limbs	Patient imaging data (CT, MRI, etc.)	Both accept DICOM imaging data
Output Data	3D bone models, alignment angles, semi-automated osteotomy plan, printable reports	Visualization of anatomy and planning tools	Equivalent in purpose; SkeletonPlanner adds automation and structured reporting
Principle of Operation	Semi-automated algorithms reconstruct 3D models, identify landmarks, calculate angles, propose osteotomy plan; surgeon customizes and confirms plan	User interacts with software to visualize and plan procedures	Same principle: software-based visualization and surgical planning
Deep Learning Component	nnU-Net for automated femur/tibia segmentation; clinician review required prior to use	Not specified	Enhancement to workflow efficiency; clinician confirmation required; does not alter intended use
User Interface	GUI with tabbed navigation; interactive 3D viewer	GUI with visualization and planning tools	Both provide GUI interfaces
Intended	Radiologists and	Radiologists and	**Same**

Feature / Characteristic	SkeletonPlanner (Presurgeo)	Predicate – SurgiCase Viewer (K213684)	Comparison / Notes
Users	orthopedic surgeons	orthopedic surgeons	
Patient Population	Skeletally mature patients ≥18 years	Patients requiring orthopedic surgical planning	Same population; SkeletonPlanner explicitly scoped to adults ≥18 years
Energy Source	Standard computing resources	Standard computing resources	**Same**
Materials	Software only	Software only	**Same**
Risk Controls	Software V&V, usability testing, cybersecurity risk analysis, risk management (ISO 14971), labeling, training	Software V&V, labeling	SkeletonPlanner adds cybersecurity and usability safeguards
Regulatory Compliance	FDA QSR, ISO 13485 (BSI Certificate MD 548540)	FDA QSR, ISO 13485	**Same**

8. **Summary of Nonclinical Performance Testing** *(per 21 CFR 807.92(b)(1))*

   Nonclinical performance testing was conducted to verify and validate SkeletonPlanner against design specifications and applicable consensus standards. Testing included:

   - **Software Verification & Validation** (IEC 62304)
   - **Segmentation Accuracy:**
     - *Observed:* DSC > 0.97
     - *Acceptance Criterion:* DSC ≥ 0.95
   - **Landmark Identification Accuracy:**
     - *Observed:* me*an error < 2.0 mm*
     - *Acceptance Criterion:* ≤ 3.0 mm
   - **Angle Measurement Accuracy:**
     - *Observed: mean absolute error < 1.5°*
     - *Acceptance Criterion:* ≤ 3.0°
   - **Cybersecurity Testing** (CVSS v4.0; penetration testing, fuzzing, vulnerability scanning)
   - **Human Factors / Usability Validation** (IEC 62366; representative users; all critical tasks completed safely)
   - **Risk Management** (ISO 14971)

   All testing met acceptance criteria.

9. **Summary of Clinical Performance Testing** *(per 21 CFR 807.92(b)(2))*

   No clinical performance testing was conducted. No clinical performance testing was conducted. Usability

validation was performed under simulated-use conditions with representative users. These studies constitute nonclinical performance testing and do not meet the definition of a clinical investigation under 21 CFR 812.28.

10. Statement of Substantial Equivalence

SkeletonPlanner (Presurgeo, Uplanner B.V.) is substantially equivalent to the predicate SurgiCase Viewer (K213684). Both devices share the same intended use, regulatory classification, device type, and fundamental operating principles. Differences in automation, deployment architecture, and product code do not raise new questions of safety or effectiveness. Nonclinical performance testing supports the safety and effectiveness of the subject device for its intended use.

This 510(k) Summary has been prepared in accordance with 21 CFR 807.92.