



July 7, 2025

CustomSurg AG
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
SAINT PAUL, MINNESOTA 55114

Re: K251863

Trade/Device Name: CustomSurg OrthoPlanner
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 17, 2025
Received: June 17, 2025

Dear Prithul Bom:

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,

 for

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

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.

K251863

?

Please provide the device trade name(s).

?

CustomSurg OrthoPlanner

Please provide your Indications for Use below.

?

CustomSurg OrthoPlanner is a software system designed to help surgeons carry out pre-operative planning for surgical procedures, based on their patients' imaging studies.

The software imports diagnostic imaging studies such as x-rays and CT images. In parallel, there is a database of digital representations related to implant materials supplied by their producing companies.

The software can process an imported 3D model of the patient's CT scan to digitally perform the surgical planning. Experience in usage and a clinical assessment are necessary for proper use of the software.

CustomSurg OrthoPlanner is to be used in conjunction with the planned device's instructions for use, the patient's clinical history, symptoms, and other pre-procedural evaluations by a surgeon who is responsible for making all final patient management decisions.

It is not intended to replace the planned device's instructions for use.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

?

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	CustomSurg AG
Applicant Address	Bubenbergstrasse 1 Zurich ZH 8045 Switzerland
Applicant Contact Telephone	+41786278853
Applicant Contact	Dr. Thomas Zumbrunn
Applicant Contact Email	thomas@customsurg.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	CustomSurg OrthoPlanner
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Product Code(s)	LLZ

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K182464	PeekMed	LLZ

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

CustomSurg OrthoPlanner is a medical software that supports surgeons in orthopedic pre-surgical planning in the musculoskeletal system in a healthcare environment. It is a web-based application that allows surgeons to upload the required data, provide details of planning the surgery and receive 3D visualization of the submitted plan. To properly use the device, clinical judgment and experience is mandatory and it shall be used in conjunction with diagnostic tools. CustomSurg OrthoPlanner does not perform any diagnostic evaluations and will not have intra-operative functionality.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

CustomSurg OrthoPlanner is a software system designed to help surgeons carry out pre-operative planning for surgical procedures, based on their patients' imaging studies. The software imports diagnostic imaging studies such as x-rays and CT images. In parallel, there is a database of digital representations related to implant materials supplied by their producing companies. The software can process an imported 3D model of the patient's CT scan to digitally perform the surgical planning. Experience in usage and a clinical assessment are necessary for proper use of the software. CustomSurg OrthoPlanner is to be used in conjunction with the planned device's instructions for use, the patient's clinical history, symptoms, and other pre-procedural evaluations by a surgeon who is responsible for making all final patient management decisions. It is not intended to replace the planned device's instructions for use.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

CustomSurg believes the CustomSurg OrthoPlanner is substantially equivalent to the predicate device based on the information summarized below.

Indications for Use Comparison

The differences between the indications for use of PeekMed and CustomSurg OrthoPlanner are:

- PeekMed supports importing medical images directly from PACS while CustomSurg OrthoPlanner does not have a direct PACS interface.
- PeekMed supports the use of MRI medical images while CustomSurg OrthoPlanner does not.

The differences specified above do not constitute a new intended purpose because they only regard clinically irrelevant features, the image import feature. The intended purpose of both the device and its predicate is to serve as a support tool for surgery planning. It can be concluded that the differences do not raise new questions of safety and effectiveness of the device compared to the predicate.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

Technological Comparison

The device and its predicate are both medical software that allow surgeons to perform orthopedic pre-surgical planning in the musculoskeletal system in a healthcare environment, therefore share the same intended use, same intended user and a similar intended population. To properly use both devices, clinical judgment and experience is mandatory. Both devices have similar workflows, use requirements (e.g. internet connection, output validation), planning features (e.g., model representation, digital representation of prosthetic material). Neither the device nor its predicate use artificial intelligence (AI).

All technological characteristics of the CustomSurg OrthoPlanner have been substantiated by the predicate device. Any technological differences have been assessed and determined to not raise new questions of safety and effectiveness. As such, the CustomSurg OrthoPlanner and PeekMed have been determined to be substantially equivalent.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Results from internal verification and validation testing performed in accordance with CustomSurg's design control processes confirm that the CustomSurg OrthoPlanner product specifications have been met. Acceptance criteria were achieved for all tests. Supporting documentation is included in this 510(k) Premarket Notification and supports the claims of substantial equivalence to the predicate device.

A risk analysis in accordance with ISO 14971 was completed as part of the software design and development effort.

Not Applicable

CustomSurg OrthoPlanner, as designed and developed by CustomSurg AG, is determined to be substantially equivalent to the predicate device. Differences between the two devices do not raise new questions about the safety and effectiveness of CustomSurg OrthoPlanner.