

K251863 CustomSurg OrthoPlannerJul 7, 2025
20 days to decisionK251863 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k251863/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 17, 2025
Decision date	Jul 7, 2025
Days to decision	20 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Customsurg AG
Location	Zurich, CH
Contact	Thomas Zumbrunn
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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