FDA 510(k) Premarket Notification

K251863 CustomSurg OrthoPlanner

CLEARED

Jul 7, 2025
20 days to decision

K251863 · 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