FDA 510(k) Premarket Notification

K252133 Adaptix Ortho350

CLEARED

Nov 6, 2025
122 days to decision

K252133 · Product code: **IZF** · Radiology
Source: https://www.510kdatabase.net/k252133/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomographic (IZF)
Date received	Jul 7, 2025
Decision date	Nov 6, 2025
Days to decision	122 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Adaptix Limited**
Location	Oxford, GB
Contact	Martin Stofanko
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