FDA 510(k) Premarket Notification

K242552 Horos Mobile

CLEARED

Apr 8, 2025
224 days to decision

K242552 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k242552/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 27, 2024
Decision date	Apr 8, 2025
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Icat Solutions, Ltd.**
Location	Norwich, GB
Contact	Georgios Michalopoulos
510(k) history	2 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	**Medical Device Academy, Inc.**
Contact	Bhoomika Joyappa

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