FDA 510(k) Premarket Notification

CLEARED

K244049 Europa (Alternative: AiRTouch) portable X-ray system

May 28, 2025
148 days to decision

K244049 · Product code: **IZL** · Radiology
Source: https://www.510kdatabase.net/k244049/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Dec 31, 2024
Decision date	May 28, 2025
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Livermoretech, Inc.**
Location	Plano, TX, US
Contact	Casey Lee
510(k) history	6 submissions · 6 cleared · 2018-2025

REGULATORY CONSULTANT

Consulting firm	**Mtech Group, LLC**
Contact	Dave Kim

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