FDA 510(k) Premarket Notification

K242838 QuickRad

CLEARED

Feb 21, 2025
155 days to decision

K242838 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k242838/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 19, 2024
Decision date	Feb 21, 2025
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aikenist Technologies Pvt, Ltd.**
Location	Bengaluru, IN
Contact	Ashwin Amarapuram Chandramouly
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**David Dills**
Contact	David Dills

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