FDA 510(k) Premarket Notification

K212940 Skanmobile, Skanmobile-Dr

CLEARED

Mar 4, 2022
170 days to decision

K212940 · Product code: **IZL** · Radiology
Source: https://www.510kdatabase.net/k212940/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Sep 15, 2021
Decision date	Mar 4, 2022
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Skanray Technologies Limited**
Location	Mysore, IN
Contact	Vasundhara R
510(k) history	4 submissions · 4 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	**IZiel Healthcare**
Contact	Ankur Naik

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