

K212940 Skanmobile, Skanmobile-DrMar 4, 2022
170 days to decisionK212940 · 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	Skansray 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.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212940/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026