FDA 510(k) Premarket Notification

K220518 SKANRAD 400

CLEARED

Apr 1, 2022
37 days to decision

K220518 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k220518/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Feb 23, 2022
Decision date	Apr 1, 2022
Days to decision	37 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