FDA 510(k) Premarket Notification

K230241 Jumong General

CLEARED

Feb 23, 2023
24 days to decision

K230241 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k230241/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Stationary (KPR)
Date received	Jan 30, 2023
Decision date	Feb 23, 2023
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sg Healthcare Co, Ltd.**
Location	Hanam-Si Gyeonggi-Do, KR
Contact	Byung Ju Kang
510(k) history	3 submissions · 3 cleared · 2015-2023

REGULATORY CONSULTANT

Consulting firm	**Kamm & Associates**
Contact	Daniel Kamm

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