FDA 510(k) Premarket Notification

K212144 Remex KA6

CLEARED

Aug 3, 2021
25 days to decision

K212144 · Product code: **IZL** · Radiology
Source: https://www.510kdatabase.net/k212144/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Jul 9, 2021
Decision date	Aug 3, 2021
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Remedi Co., Ltd.**
Location	Seoul, KR
Contact	Suho Cho
510(k) history	3 submissions · 3 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	**510K FDA, Inc.**
Contact	W. Lee Strong

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