FDA 510(k) Premarket Notification

K211423 Rover

CLEARED

May 21, 2021
14 days to decision

K211423 · Product code: **IZL** · Radiology
Source: https://www.510kdatabase.net/k211423/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Mobile (IZL)
Date received	May 7, 2021
Decision date	May 21, 2021
Days to decision	14 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Micro-X Limited**
Location	Cloverly Park, AU
Contact	Derek Rogers
510(k) history	1 submissions · 1 cleared · 2021-2021

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k211423/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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