

K201488 RoverJul 17, 2020
43 days to decisionK201488 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k201488/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, X-ray, Mobile (IZL)
Date received	Jun 4, 2020
Decision date	Jul 17, 2020
Days to decision	43 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Micro-X , Ltd.
Location	Tonsley (Clovelly Park), AU
Contact	Mark Norman
510(k) history	1 submissions · 1 cleared · 2020-2020

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.netDevice record: <https://www.510kdatabase.net/k201488/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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