

K210479 IMPACT and X-RangerMar 19, 2021
28 days to decisionK210479 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k210479/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Mobile (IZL)
Date received	Feb 19, 2021
Decision date	Mar 19, 2021
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Minxray, Inc.
Location	Mchenry, IL, US
Contact	Keith Kretchmer
510(k) history	18 submissions · 18 cleared · 1976-2021

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

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