

K221081 iQFlex M Mobile X-ray System, iQFlex MD Mobile X-ray SystemJun 13, 2022
62 days to decisionK221081 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k221081/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Apr 12, 2022
Decision date	Jun 13, 2022
Days to decision	62 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	First Source, Inc.
Location	Rochester, NY, US
Contact	Ronald Viola
510(k) history	3 submissions · 3 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	Medmonts Co., Ltd.
Contact	Woo Sung Park

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221081/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026