FDA 510(k) Premarket Notification

CLEARED

K221081 iQFlex M Mobile X-ray System, iQFlex MD Mobile X-ray System

Jun 13, 2022
62 days to decision

K221081 · 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