FDA 510(k) Premarket Notification

K240009 iQFlex Pro

CLEARED

Jul 3, 2024
183 days to decision

K240009 · Product code: **IZL** · Radiology
Source: https://www.510kdatabase.net/k240009/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Jan 2, 2024
Decision date	Jul 3, 2024
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**First Source, Inc.**
Location	Rochester, NY, US
Contact	Woo Sung Park
510(k) history	3 submissions · 3 cleared · 2021-2024