FDA 510(k) Premarket Notification

K223550 DMX

CLEARED

Apr 10, 2023
136 days to decision

K223550 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k223550/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, X-ray, Stationary (KPR)
Date received	Nov 25, 2022
Decision date	Apr 10, 2023
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Del Medical, Inc.**
Location	Naples, FL, US
Contact	Greg Geary
510(k) history	4 submissions · 4 cleared · 2014-2023

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