FDA 510(k) Premarket Notification

K233920 EOSedge

CLEARED

Aug 6, 2024
237 days to decision

K233920 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k233920/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Dec 13, 2023
Decision date	Aug 6, 2024
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Eos Imaging**
Location	Washington, Dc, DC, US
Contact	Mathilde Masurel
510(k) history	15 submissions · 15 cleared · 2012-2025