FDA 510(k) Premarket Notification

K233669 OEC 3D

CLEARED

Mar 28, 2024
134 days to decision

K233669 · Product code: **OXO** · Radiology
Source: https://www.510kdatabase.net/k233669/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image-intensified Fluoroscopic X-ray System, Mobile (OXO)
Date received	Nov 15, 2023
Decision date	Mar 28, 2024
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Oec Medical Systems, Inc.**
Location	Salt Lake City, UT, US
Contact	Shawn Quigley
510(k) history	11 submissions · 11 cleared · 2004-2024