FDA 510(k) Premarket Notification

K241300 ViewPoint 6

CLEARED

Jul 2, 2024
54 days to decision

K241300 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k241300/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 9, 2024
Decision date	Jul 2, 2024
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Healthcare GmbH**
Location	M?nchen, DE
Contact	Brandon O'Shea
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**GE Healthcare**
Contact	Brandon O'Shea

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov