FDA 510(k) Premarket Notification

K222717 CL24N

CLEARED

Oct 31, 2022
53 days to decision

K222717 · Product code: **PGY** · Radiology
Source: https://www.510kdatabase.net/k222717/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Sep 8, 2022
Decision date	Oct 31, 2022
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wide Corporation**
Location	Denton, TX, US
Contact	YeoJin Yun
510(k) history	20 submissions · 20 cleared · 2003-2023

REGULATORY CONSULTANT

Consulting firm	**Ot Consulting, Inc.**
Contact	Josh Baker

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