

K222716 MX50NMay 8, 2023
242 days to decisionK222716 · Product code: **PGY** · Radiology
Source: <https://www.510kdatabase.net/k222716/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Sep 8, 2022
Decision date	May 8, 2023
Days to decision	242 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
Contact	Josh Baker

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

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