FDA 510(k) Premarket Notification

K223423 32HQ713D

CLEARED

Mar 1, 2023
107 days to decision

K223423 · Product code: **PGY** · Radiology
Source: https://www.510kdatabase.net/k223423/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Nov 14, 2022
Decision date	Mar 1, 2023
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lg Electronics.Inc**
Location	Pyeongtaek-Si, KR
Contact	Jinhwan Jun
510(k) history	26 submissions · 26 cleared · 2018-2025

REGULATORY CONSULTANT

Consulting firm	**Gms Consulting**
Contact	JongHyun Kim

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