

K212295 21HQ513DDec 3, 2021
134 days to decisionK212295 · Product code: **PGY** · Radiology
Source: <https://www.510kdatabase.net/k212295/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Jul 22, 2021
Decision date	Dec 3, 2021
Days to decision	134 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	DoGyun Im

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

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