

K221061 21HQ613DJun 3, 2022
53 days to decisionK221061 · Product code: **PGY** · Radiology
Source: <https://www.510kdatabase.net/k221061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Apr 11, 2022
Decision date	Jun 3, 2022
Days to decision	53 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](https://accessdata.fda.gov)

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