

K260320 Lunit INSIGHT MMG (v1.1.10)Apr 23, 2026
83 days to decisionK260320 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k260320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ)
Date received	Jan 30, 2026
Decision date	Apr 23, 2026
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lunit, Inc.
Location	Seoul, KR
Contact	Sulgue Choi
510(k) history	6 submissions · 6 cleared · 2021-2026

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