

K211678 Lunit INSIGHT MMGNov 17, 2021
169 days to decisionK211678 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k211678/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ)
Date received	Jun 1, 2021
Decision date	Nov 17, 2021
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	John Smith

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

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