

K231470 Lunit INSIGHT DBTNov 6, 2023
168 days to decisionK231470 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k231470/>**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	May 22, 2023
Decision date	Nov 6, 2023
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231470/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026