

K253796 Lunit INSIGHT DBT (V1.2)

Mar 26, 2026
118 days to decision

K253796 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k253796/>

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	Nov 28, 2025
Decision date	Mar 26, 2026
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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