

K242652 Lunit INSIGHT DBT v1.1

Oct 4, 2024
30 days to decision

K242652 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k242652/>

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	Sep 4, 2024
Decision date	Oct 4, 2024
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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