FDA 510(k) Premarket Notification

K231470 Lunit INSIGHT DBT

CLEARED

Nov 6, 2023
168 days to decision

K231470 · 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