FDA 510(k) Premarket Notification

K211733 Lunit INSIGHT CXR Triage

CLEARED

Nov 10, 2021
159 days to decision

K211733 · Product code: **QFM** · Radiology
Source: https://www.510kdatabase.net/k211733/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Jun 4, 2021
Decision date	Nov 10, 2021
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells**
Contact	Colin S. Jacob

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