FDA 510(k) Premarket Notification

K251769 RevealAI-Lung

CLEARED

Jan 30, 2026
234 days to decision

K251769 · Product code: **POK** · Radiology
Source: https://www.510kdatabase.net/k251769/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Jun 10, 2025
Decision date	Jan 30, 2026
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Precision Medical Ventures, Inc. Dba Revealdx**
Location	Seattle, WA, US
Contact	Michael Calhoun
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US Lpp**
Contact	Michael Calhoun

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