FDA 510(k) Premarket Notification

K252735 C-beam

CLEARED

May 22, 2026
267 days to decision

K252735 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k252735/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Aug 28, 2025
Decision date	May 22, 2026
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pulmera, Inc.**
Location	Palo Alto, CA, US
Contact	Bryan Hartley
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Innovative Product Advocates**
Contact	Kyle O'Sullivan

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