

K252735 C-beamMay 22, 2026
267 days to decisionK252735 · 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](https://accessdata.fda.gov)

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