

K251532 Acorn 3D Software (AC-SEG-4009)Nov 3, 2025
168 days to decisionK251532 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k251532/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 19, 2025
Decision date	Nov 3, 2025
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Acorn 3DP Model (AC-101-XX)

APPLICANT

Company	Mighty Oak Medical
Location	Englewood, CO, US
Contact	Mark Wylie
510(k) history	4 submissions · 4 cleared · 2024-2026

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