

K252103 Acorn 3D Software (AC-SEG-4009)Dec 2, 2025
152 days to decisionK252103 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k252103/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 3, 2025
Decision date	Dec 2, 2025
Days to decision	152 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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