

K260322 Acorn 3D Software (AC-SEG-4009)Jun 11, 2026
132 days to decisionK260322 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k260322/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jan 30, 2026
Decision date	Jun 11, 2026
Days to decision	132 days
Third-party review	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	5 submissions · 5 cleared · 2024-2026

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Device record: <https://www.510kdatabase.net/k260322/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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