

K234009 Acorn 3D Software (AC-SEG-4009)Jul 12, 2024
206 days to decisionK234009 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k234009/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 19, 2023
Decision date	Jul 12, 2024
Days to decision	206 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
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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