FDA 510(k) Premarket Notification

K260322 Acorn 3D Software (AC-SEG-4009)

CLEARED

Jun 11, 2026
132 days to decision

K260322 · 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