

**K242359 Strain AI (SAI001)**Nov 20, 2024  
103 days to decisionK242359 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k242359/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Aug 9, 2024
Decision date	Nov 20, 2024
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Exo, Inc.</b>
Location	Walker, MI, US
Contact	Murray Jacqueline
510(k) history	5 submissions · 5 cleared · 1983-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242359/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026