

K251766 TumorSight VizJul 8, 2025
29 days to decisionK251766 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k251766/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jun 9, 2025
Decision date	Jul 8, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	SimBioSys, Inc.
Location	Chicago, IL, US
Contact	Kimberly Oleson
510(k) history	3 submissions · 3 cleared · 2023-2025

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