

K243189 TumorSight VizOct 25, 2024
25 days to decisionK243189 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k243189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Sep 30, 2024
Decision date	Oct 25, 2024
Days to decision	25 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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