

K231130 TumorSight VizDec 26, 2023
250 days to decisionK231130 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k231130/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 20, 2023
Decision date	Dec 26, 2023
Days to decision	250 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Hogan & Lovells U.S. Lpp
Contact	John J. Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231130/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026