FDA 510(k) Premarket Notification

K231130 TumorSight Viz

CLEARED

Dec 26, 2023
250 days to decision

K231130 · 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