

K241083 SIS SystemJun 14, 2024
56 days to decisionK241083 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k241083/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 19, 2024
Decision date	Jun 14, 2024
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Surgical Information Sciences, Inc.
Location	Minneapolis, MN, US
Contact	Ann Quinlan-Smith
510(k) history	7 submissions · 7 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Kelliann Payne

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/k241083/> 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 14, 2026