

**K223032 SIS System (Version 5.6.0)**Nov 21, 2022  
53 days to decisionK223032 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k223032/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Sep 29, 2022
Decision date	Nov 21, 2022
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Kelliann H 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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223032/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026