

K210071 SIS System (Version 5.1.0)Mar 31, 2021
79 days to decisionK210071 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k210071/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 11, 2021
Decision date	Mar 31, 2021
Days to decision	79 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 H. Payne

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210071/> 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