FDA 510(k) Premarket Notification

K223032 SIS System (Version 5.6.0)

CLEARED

Nov 21, 2022
53 days to decision

K223032 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k223032/

SUBMISSION DETAILS

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

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.gov