

K210556 Preview ShoulderApr 21, 2021
55 days to decisionK210556 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k210556/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Feb 25, 2021
Decision date	Apr 21, 2021
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Genesis Software Innovations
Location	Grand Rapids, MI, US
Contact	Matt Miller
510(k) history	2 submissions · 2 cleared · 2021-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210556/> 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 27, 2026