

# K210747 Caption Interpretation Automated Ejection Fraction Software

Jan 19, 2022  
313 days to decisionK210747 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k210747/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Mar 12, 2021
Decision date	Jan 19, 2022
Days to decision	313 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Caption Health</b>
Location	Brisbane, CA, US
Contact	Sam Surette
510(k) history	4 submissions · 4 cleared · 2020-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Manatt, Phelps, &amp; Phillips, Llp</b>
Contact	Savannah Hari

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](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210747/>; 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 27, 2026