

K200621 Caption Interpretation Automated Ejection Fraction SoftwareJul 22, 2020
135 days to decisionK200621 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k200621/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Mar 9, 2020
Decision date	Jul 22, 2020
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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