

K201992 Caption GuidanceSep 18, 2020
63 days to decisionK201992 · Product code: **QJU** · Radiology
Source: <https://www.510kdatabase.net/k201992/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image Acquisition And/or Optimization Guided By Artificial Intelligence (QJU)
Date received	Jul 17, 2020
Decision date	Sep 18, 2020
Days to decision	63 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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