

**K192167 CuraRad-ICH**Apr 13, 2020  
248 days to decisionK192167 · Product code: **QAS** · Radiology  
Source: <https://www.510kdatabase.net/k192167/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Aug 9, 2019
Decision date	Apr 13, 2020
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Curacloud Corp.</b>
Location	Seattle, WA, US
Contact	Xiaoxiao Liu
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Manatt, Phelps, &amp; Phillips, Llp</b>
Contact	Yarmela Pavlovic

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192167/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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