

**K211222 qER-Quant**Jul 30, 2021  
98 days to decisionK211222 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k211222/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 23, 2021
Decision date	Jul 30, 2021
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Qure.Ai Technologies</b>
Location	Mumbai, IN
Contact	Pooja Rao
510(k) history	9 submissions · 9 cleared · 2020-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Qure.ai</b>
Contact	Pooja Rao

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211222/> 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 26, 2026