

**K192437 Arterys MICA**Mar 25, 2020  
201 days to decisionK192437 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k192437/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Sep 6, 2019
Decision date	Mar 25, 2020
Days to decision	201 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Arterys, Inc.</b>
Location	San Francisco, CA, US
Contact	Sharon Cholowsky
510(k) history	8 submissions · 8 cleared · 2016-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192437/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026