

**K220080 CogNet QmTRIAGE**Sep 29, 2022  
262 days to decisionK220080 · Product code: **QFM** · Radiology  
Source: <https://www.510kdatabase.net/k220080/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Jan 10, 2022
Decision date	Sep 29, 2022
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medcognetics, Inc.</b>
Location	Dallas, TX, US
Contact	Diane Rutherford
510(k) history	2 submissions · 2 cleared · 2022-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220080/> 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