

**K200438 MPS 3 Myocardial Protection System**Jun 19, 2020  
116 days to decisionK200438 · Product code: **DTR** · Cardiovascular  
Source: <https://www.510kdatabase.net/k200438/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Feb 24, 2020
Decision date	Jun 19, 2020
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Quest Medical, Inc.</b>
Location	Walker, MI, US
Contact	Tosan Onosode
510(k) history	39 submissions · 39 cleared · 1980-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200438/> 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 14, 2026