

K201984 MPS 3 ND Myocardial Protection SystemNov 20, 2020
126 days to decisionK201984 · Product code: **DTR** · Cardiovascular
Source: <https://www.510kdatabase.net/k201984/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Jul 17, 2020
Decision date	Nov 20, 2020
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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