

K200374 Columbus GuidewireDec 14, 2020
304 days to decisionK200374 · Product code: **MOF** · Neurology
Source: <https://www.510kdatabase.net/k200374/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Guide, Wire, Catheter, Neurovasculature (MOF)
Date received	Feb 14, 2020
Decision date	Dec 14, 2020
Days to decision	304 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rapid Medical , Ltd.
Location	Yokneam, IL
Contact	Orit Yaniv
510(k) history	9 submissions · 7 cleared · 2019-2026

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice Hogan

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

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