

K201652 COBRA-OS KitFeb 22, 2021
249 days to decisionK201652 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k201652/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Jun 18, 2020
Decision date	Feb 22, 2021
Days to decision	249 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Front Line Medical Technologies, Inc.
Location	London, CA
Contact	Asha Parekh
510(k) history	1 submissions · 0 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Covance
Contact	Sharon Iverson

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

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