

K203670 Extra Large Check-Flo IntroducerFeb 16, 2021
62 days to decisionK203670 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k203670/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Dec 16, 2020
Decision date	Feb 16, 2021
Days to decision	62 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cook Incorporated
Location	Bloomington, IN, US
Contact	Reuben Lidster
510(k) history	175 submissions · 153 cleared · 2006-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203670/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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