

K180054 Royal Flush Plus High-Flow CatheterOct 5, 2018
270 days to decisionK180054 · Product code: **DQO** · Cardiovascular
Source: <https://www.510kdatabase.net/k180054/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Jan 8, 2018
Decision date	Oct 5, 2018
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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