

K210734 Endovascular Dilator and SetsApr 6, 2021
26 days to decisionK210734 · Product code: **DRE** · CardiovascularSource: <https://www.510kdatabase.net/k210734/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Mar 11, 2021
Decision date	Apr 6, 2021
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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