

K221414 ENROUTE Enflate Transcarotid RX Balloon Dilatation CatheterSep 2, 2022
109 days to decisionK221414 · Product code: **LIT** · Cardiovascular
Source: <https://www.510kdatabase.net/k221414/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	May 16, 2022
Decision date	Sep 2, 2022
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Silk Road Medical, Inc.
Location	Sunnyvale, CA, US
Contact	Denise Aycox
510(k) history	5 submissions · 5 cleared · 2013-2022

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