

K221832 SABER .014 PTA Dilatation CatheterAug 22, 2022
60 days to decisionK221832 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k221832/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jun 23, 2022
Decision date	Aug 22, 2022
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SABERX .014 PTA Dilatation Catheter

APPLICANT

Company	Cordis US Corp
Location	Miami Lakes, FL, US
Contact	Luis Davila
510(k) history	4 submissions · 4 cleared · 2022-2024

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