

K191275 All'InCath 035M PTA Balloon Dilatation CatheterJan 15, 2020
247 days to decisionK191275 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k191275/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	May 13, 2019
Decision date	Jan 15, 2020
Days to decision	247 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nexstep Medical
Location	Dijon, FR
Contact	Angela Mallery
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Namsa
Contact	Angela Mallery

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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