FDA 510(k) Premarket Notification

K191275 All'InCath 035M PTA Balloon Dilatation Catheter

CLEARED

Jan 15, 2020
247 days to decision

K191275 · 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