

K211134 BIB Stent Placement CatheterMay 27, 2021
41 days to decisionK211134 · Product code: **NVM** · CardiovascularSource: <https://www.510kdatabase.net/k211134/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal, Dual-balloon (NVM)
Date received	Apr 16, 2021
Decision date	May 27, 2021
Days to decision	41 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	NuMED, Inc.
Location	Hopkinton, NY, US
Contact	Nichelle LaFlesh
510(k) history	49 submissions · 47 cleared · 1985-2022

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