

K213915 BIB Stent Placement CatheterJan 12, 2022
28 days to decisionK213915 · Product code: **NVM** · CardiovascularSource: <https://www.510kdatabase.net/k213915/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal, Dual-balloon (NVM)
Date received	Dec 15, 2021
Decision date	Jan 12, 2022
Days to decision	28 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213915/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026