FDA 510(k) Premarket Notification

# K213915 BIB Stent Placement Catheter

**CLEARED**

Jan 12, 2022
28 days to decision

K213915 · Product code: **NVM** · Cardiovascular
Source: https://www.510kdatabase.net/k213915/

## SUBMISSION DETAILS

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|---|---|
| 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 |