

**K050857 BIB PTA BALLOON CATHETER**

Jul 28, 2005  
114 days to decision

K050857 · Product code: **NVM** · Cardiovascular  
Source: <https://www.510kdatabase.net/k050857/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal, Dual-balloon (NVM)
Date received	Apr 5, 2005
Decision date	Jul 28, 2005
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>NuMED, Inc.</b>
Location	Hopkinton, NY, US
Contact	JODI GIJANTO
510(k) history	49 submissions · 47 cleared · 1985-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k050857/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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