

K131869 PTS-X SIZING BALLOON CATHETERAug 8, 2013
45 days to decisionK131869 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k131869/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Jun 24, 2013
Decision date	Aug 8, 2013
Days to decision	45 days
Third-party review	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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