

K121859 TYSHAK NUCLEUSAug 31, 2012
66 days to decisionK121859 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k121859/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 26, 2012
Decision date	Aug 31, 2012
Days to decision	66 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121859/> 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 14, 2026