FDA 510(k) Premarket Notification

K121859 TYSHAK NUCLEUS

CLEARED

Aug 31, 2012
66 days to decision

K121859 · 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