FDA 510(k) Premarket Notification

K082868 MULLINS-X, MODEL 250X

CLEARED

Oct 24, 2008
25 days to decision

K082868 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k082868/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 29, 2008
Decision date	Oct 24, 2008
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**NuMED, Inc.**
Location	Hopkinton, NY, US
Contact	NICHELLE LAFLESH
510(k) history	49 submissions · 47 cleared · 1985-2022