FDA 510(k) Premarket Notification

K160598 REBOA Balloon Catheter

CLEARED

Jun 20, 2016
110 days to decision

K160598 · Product code: **MJN** · Cardiovascular
Source: https://www.510kdatabase.net/k160598/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Mar 2, 2016
Decision date	Jun 20, 2016
Days to decision	110 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