FDA 510(k) Premarket Notification

K123445 NMI COAXIAL MICROINTRODUCER SET

CLEARED

Apr 1, 2013
144 days to decision

K123445 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k123445/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Nov 8, 2012
Decision date	Apr 1, 2013
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Navilyst Medical, Inc.**
Location	Marlborough, MA, US
Contact	WANDA CARPINELLA
Website	http://www.navilystmedical.com/
510(k) history	35 submissions · 33 cleared · 2009-2017