FDA 510(k) Premarket Notification

K132713 NMI COAXIAL MICROINTRODUCER SET

CLEARED

Sep 27, 2013
28 days to decision

K132713 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k132713/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Aug 30, 2013
Decision date	Sep 27, 2013
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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