FDA 510(k) Premarket Notification

K062554 STARCLOSE HEX-HUB DILATOR

CLEARED

Feb 6, 2007
160 days to decision

K062554 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k062554/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Aug 30, 2006
Decision date	Feb 6, 2007
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Abbott Vascular, Inc.**
Location	Redwood, CA, US
Contact	Daun Putnam
510(k) history	20 submissions · 17 cleared · 2000-2014