FDA 510(k) Premarket Notification

K103421 ARSTASIS DILATOR ADAPTER

CLEARED

May 24, 2011
183 days to decision

K103421 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k103421/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Nov 22, 2010
Decision date	May 24, 2011
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Arstasis, Inc.**
Location	San Carlos, CA, US
Contact	DEBRA COGAN
510(k) history	14 submissions · 14 cleared · 2010-2015