FDA 510(k) Premarket Notification

K132263 AXERA 2 ACCESS SYSTEM

CLEARED

Aug 19, 2013
28 days to decision

K132263 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k132263/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jul 22, 2013
Decision date	Aug 19, 2013
Days to decision	28 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