FDA 510(k) Premarket Notification

K140201 AXERA 2 ACCESS SYSTEM

CLEARED

Mar 28, 2014
60 days to decision

K140201 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k140201/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jan 27, 2014
Decision date	Mar 28, 2014
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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