FDA 510(k) Premarket Notification

K161362 ASAHI Corsair Armet

CLEARED

Jun 14, 2016
29 days to decision

K161362 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k161362/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	May 16, 2016
Decision date	Jun 14, 2016
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Asahi Intecc Co., Ltd.**
Location	Seto-Shi, JP
Contact	Carroll Councilman
Website	https://www.asahi-intecc.com
510(k) history	83 submissions · 83 cleared · 2003-2026