FDA 510(k) Premarket Notification

K061601 ASAHI PRECIOUS GUIDE CATHETER

CLEARED

Nov 17, 2006
162 days to decision

K061601 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k061601/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 8, 2006
Decision date	Nov 17, 2006
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Asahi Intecc Co., Ltd.**
Location	Seto-Shi, JP
Contact	YOSHI TERAI
Website	https://www.asahi-intecc.com
510(k) history	84 submissions · 84 cleared · 2003-2026