FDA 510(k) Premarket Notification

CLEARED

K122468 ASAHI PTCA GUIDE WIRE ASAHI SION BLUE 180CM ASAHI PTCA GUIDE WIRE ASAHI SION BLUE 3300CM ASAHI PTCA GUIDE WIRE ASAHI SIO

Mar 8, 2013
207 days to decision

K122468 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k122468/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Aug 13, 2012
Decision date	Mar 8, 2013
Days to decision	207 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k122468/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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