

**K100578 ASAHI SION PTCA GUIDE WIRE MODEL AHW14R001S
& AHW14R301S**Sep 22, 2010
205 days to decisionK100578 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k100578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Mar 1, 2010
Decision date	Sep 22, 2010
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100578/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 20, 2026