FDA 510(k) Premarket Notification

K211898 ASAHI PCI Guide Wire ASAHI CONFIANZA PRO 8-20

CLEARED

Dec 8, 2021
170 days to decision

K211898 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k211898/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jun 21, 2021
Decision date	Dec 8, 2021
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Asahi Intecc USA, Inc.**
Contact	Cynthia Valenzuela

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT02379923

The Asahi Intecc PTCA Chronic Total Occlusion Study

Status	Completed
Enrollment	163 patients (actual)
Study sites	12 sites
Condition studied	Coronary Artery Disease; Coronary Artery Chronic Total Occlusion
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jan 1, 2016
Sponsor	Asahi Intecc USA Inc (Industry)

Primary outcome

Procedure Success

Secondary outcome

Frequency of Successful Recanalization

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02379923