FDA 510(k) Premarket Notification

K221951 Branchor Balloon Guide Catheter

CLEARED

Oct 11, 2022
98 days to decision

K221951 · Product code: **QJP** · Neurology
Source: https://www.510kdatabase.net/k221951/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Jul 5, 2022
Decision date	Oct 11, 2022
Days to decision	98 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	Katsuhiko Fujimura
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