

K213868 ASAHI Gladius Mongo18 PV ESSep 6, 2022
270 days to decisionK213868 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k213868/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 10, 2021
Decision date	Sep 6, 2022
Days to decision	270 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](https://accessdata.fda.gov)

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