

K223809 PrecisionTAVI (v1.1)May 30, 2023
161 days to decisionK223809 · Product code: **QQI** · Cardiovascular
Source: <https://www.510kdatabase.net/k223809/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Cardiovascular Implant Simulation Software Device (QQI)
Date received	Dec 20, 2022
Decision date	May 30, 2023
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dasi Simulations
Location	Dublin, OH, US
Contact	Ana Minyayev
510(k) history	2 submissions · 2 cleared · 2023-2024

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