

K233975 Zoom 6F Insert CathetersApr 2, 2024
109 days to decisionK233975 · Product code: **DQO** · CardiovascularSource: <https://www.510kdatabase.net/k233975/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Dec 15, 2023
Decision date	Apr 2, 2024
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Imperative Care, Inc.
Location	Sunnyvale, CA, US
Contact	Nguyen Teri
510(k) history	17 submissions · 17 cleared · 2018-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233975/> 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 May 13, 2026