

K231248 Swan-Ganz Catheters, FloTrac sensors, ClearSight finger cuffs, HemoSphere Advanced Monitoring PlatformSep 21, 2023
143 days to decisionK231248 · Product code: **DYG** · Cardiovascular
Source: <https://www.510kdatabase.net/k231248/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Flow Directed (DYG)
Date received	May 1, 2023
Decision date	Sep 21, 2023
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Edwards Lifesciences, LLC
Location	Irvine, CA, US
Contact	Anne Lo
510(k) history	1 submissions · 1 cleared · 2023-2023

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