

**K222117 Swang-Ganz IQ pulmonary artery catheter**Dec 9, 2022  
144 days to decisionK222117 · Product code: **DYG** · CardiovascularSource: <https://www.510kdatabase.net/k222117/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Flow Directed (DYG)
Date received	Jul 18, 2022
Decision date	Dec 9, 2022
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Edwards Lifesciences, LLC</b>
Location	Irvine, CA, US
Contact	Michelle Ducca
510(k) history	2 submissions · 2 cleared · 2020-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222117/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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