

K172423 PediaSat Oximetry Catheter, PreSep Oligon Oximetry Catheter, Edwards Oximetry Central Venous Catheter (previously PreSep Oximetry Catheter)Feb 20, 2018
194 days to decisionK172423 · Product code: **DQE** · Cardiovascular
Source: <https://www.510kdatabase.net/k172423/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Oximeter, Fiber-optic (DQE)
Date received	Aug 10, 2017
Decision date	Feb 20, 2018
Days to decision	194 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Edwards Lifescience, LLC
Location	Irvine, CA, US
Contact	Bedalin T. Lugo Rodriguez
510(k) history	1 submissions · 1 cleared · 2018-2018

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