

K183413 TruWave Disposable Pressure TransducerMay 1, 2019
142 days to decisionK183413 · Product code: **DXO** · Cardiovascular
Source: <https://www.510kdatabase.net/k183413/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Pressure, Catheter Tip (DXO)
Date received	Dec 10, 2018
Decision date	May 1, 2019
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Edwards Lifesciences, LLC
Location	Irvine, CA, US
Contact	Ye Seul Kim
510(k) history	3 submissions · 3 cleared · 2019-2022

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