

**K190852 Zurich Pressure Guidewire System Model 100**Aug 14, 2019  
134 days to decisionK190852 · Product code: **DXO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k190852/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Pressure, Catheter Tip (DXO)
Date received	Apr 2, 2019
Decision date	Aug 14, 2019
Days to decision	134 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zurich Medical, Inc.</b>
Location	Plymouth, MN, US
Contact	Kin-Joe Sham
510(k) history	1 submissions · 1 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	MARK JOB

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190852/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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