FDA 510(k) Premarket Notification

CLEARED

K190852 Zurich Pressure Guidewire System Model 100

Aug 14, 2019
134 days to decision

K190852 · Product code: **DXO** · Cardiovascular
Source: https://www.510kdatabase.net/k190852/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	MARK JOB

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