

K192169 PulsioFlex Monitoring System with ProAQT SensorApr 30, 2020
265 days to decisionK192169 · Product code: **DXG** · Cardiovascular
Source: <https://www.510kdatabase.net/k192169/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Aug 9, 2019
Decision date	Apr 30, 2020
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pulsion Medical Systems SE
Location	Westbrook, CT, US
Contact	Tobias Klaempfl
Website	http://www.pulsion.com/
510(k) history	4 submissions · 4 cleared · 2012-2020

Pulsion Medical Systems SE is now part of Getinge and specializes in cardiovascular monitoring and hemodynamic measurement systems. The company operates with a manufacturing facility in Westbrook, US. Pulsion Medical Systems received FDA 510(k) clearances from total submissions, with all submissions focused on cardiovascular devices. The company's regulatory clearances span from 2012 to 2020. Notable cleared devices include the PulsioFlex Monitoring System with ProAQT Sensor and the PiCCO Catheter, which represent core technologies in hemodynamic monitoring. The company i...

REGULATORY CONSULTANT

Consulting firm	Getinge
Contact	Mark Smith

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

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Device record: <https://www.510kdatabase.net/k192169/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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