

K122121 PULSIOFLEX MONITORING SYSTEM WITH PICCO MODULEAug 2, 2012
16 days to decisionK122121 · Product code: **DXG** · Cardiovascular
Source: <https://www.510kdatabase.net/k122121/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Jul 17, 2012
Decision date	Aug 2, 2012
Days to decision	16 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pulsion Medical Systems SE
Location	Westbrook, CT, US
Contact	Jamie Sulley
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...

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