FDA 510(k) Premarket Notification

K172259 PulsioFlex Monitoring System

CLEARED

Jan 18, 2018
175 days to decision

K172259 · Product code: **DXG** · Cardiovascular
Source: https://www.510kdatabase.net/k172259/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Jul 27, 2017
Decision date	Jan 18, 2018
Days to decision	175 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	Marc Bergenthal
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	**Maquet Cardiovascular**
Contact	Mark Smith

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