

K183390 QNext and DG-PTAug 21, 2019
258 days to decisionK183390 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k183390/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Dec 6, 2018
Decision date	Aug 21, 2019
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Diagnostic Grifols, S.A.
Location	Partes Del Valles, ES
Contact	Joaquin Alberto Tamparillas
510(k) history	1 submissions · 1 cleared · 2019-2019

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