

K211485 STA- NeoPTimalDec 23, 2022
589 days to decisionK211485 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k211485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	May 13, 2021
Decision date	Dec 23, 2022
Days to decision	589 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Diagnostica Stago S.A.S
Location	Gennevilliers, FR
Contact	Pauline Vasselon
510(k) history	3 submissions · 3 cleared · 2015-2023

REGULATORY CONSULTANT

Consulting firm	Diagnostica Stago, Inc.
Contact	Anthony Dennis

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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