

K801932 HEP-TROLSep 9, 1980
28 days to decisionK801932 · Product code: **GGW** · Hematology
Source: <https://www.510kdatabase.net/k801932/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Partial Thromboplastin (GGW)
Date received	Aug 12, 1980
Decision date	Sep 9, 1980
Days to decision	28 days
Third-party review	No

APPLICANT

Company	Helena Laboratories
Location	Mchenry, IL, US
510(k) history	280 submissions · 280 cleared · 1978-2013

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Device record: <https://www.510kdatabase.net/k801932/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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