

K972316 OPUS D-DIMERSep 9, 1997
81 days to decisionK972316 · Product code: **GHH** · Hematology
Source: <https://www.510kdatabase.net/k972316/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrin Split Products (GHH)
Date received	Jun 20, 1997
Decision date	Sep 9, 1997
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Behring Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	Ruth Forstadt
510(k) history	145 submissions · 145 cleared · 1976-1997

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