

K021877 MDA D-DIMERAug 7, 2002
61 days to decisionK021877 · Product code: **GHH** · Hematology
Source: <https://www.510kdatabase.net/k021877/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrin Split Products (GHH)
Date received	Jun 7, 2002
Decision date	Aug 7, 2002
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	bioMerieux, Inc.
Location	Mchenry, IL, US
Contact	RON SANYAL
510(k) history	251 submissions · 250 cleared · 1983-2026

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