

**K861973 D-DI TEST KIT**Sep 4, 1986  
106 days to decisionK861973 · Product code: **GHH** · Hematology  
Source: <https://www.510kdatabase.net/k861973/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Fibrin Split Products (GHH)        |
| Date received         | May 21, 1986                       |
| Decision date         | Sep 4, 1986                        |
| Days to decision      | 106 days                           |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>American Bioproducts Co.</b>         |
| Location       | Parsippany, NJ, US                      |
| Contact        | LOC B LE,PHD                            |
| 510(k) history | 79 submissions · 75 cleared · 1985-1998 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k861973/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026