

**K801926 SIGMA PROCEDURE #880 FIBRINOGEN/PLASMA**Sep 9, 1980  
28 days to decisionK801926 · Product code: **KQJ** · Hematology  
Source: <https://www.510kdatabase.net/k801926/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | System, Fibrinogen Determination (KQJ) |
| Date received         | Aug 12, 1980                           |
| Decision date         | Sep 9, 1980                            |
| Days to decision      | 28 days                                |
| Third-party review    | No                                     |

**APPLICANT**

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|----------------|---|
| Company        | <b>Sigma Chemical Co.</b>   |
| Location       | Mchenry, IL, US   |
| Website        | <a href="https://www.sigmaaldrich.com">https://www.sigmaaldrich.com</a> |
| 510(k) history | 231 submissions · 231 cleared · 1976-1994                               |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k801926/>; 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 May 14, 2026