

**K954040 ASSERACHROM TOTAL PROTEIN S KIT**Nov 13, 1995  
77 days to decisionK954040 · Product code: **GGP** · Hematology  
Source: <https://www.510kdatabase.net/k954040/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Test, Qualitative And Quantitative Factor Deficiency (GGP) |
| Date received         | Aug 28, 1995   |
| Decision date         | Nov 13, 1995   |
| Days to decision      | 77 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>American Bioproducts Co.</b>         |
| Location       | Parsippany, NJ, US                      |
| Contact        | ANDREW LOC B LE                         |
| 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/k954040/> 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