

K012386 ACTICLOT PROTEIN S, MODEL 843LSep 14, 2001
49 days to decisionK012386 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k012386/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Test, Qualitative And Quantitative Factor Deficiency (GGP) |
| Date received | Jul 27, 2001 |
| Decision date | Sep 14, 2001 |
| Days to decision | 49 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | American Diagnostica, Inc. |
| Location | Greenwich, CT, US |
| Contact | JOHN B BERRYMAN |
| 510(k) history | 10 submissions · 10 cleared · 1994-2008 |

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