

**K860719 BIOTRACK PROTIME CONTROLS (BIOTRACK PROTIME TEST)**May 23, 1986  
86 days to decisionK860719 · Product code: **JPA** · Hematology  
Source: <https://www.510kdatabase.net/k860719/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                          |
| Submission type       | Traditional   |
| Device classification | System, Multipurpose For In Vitro Coagulation Studies (JPA) |
| Date received         | Feb 26, 1986  |
| Decision date         | May 23, 1986  |
| Days to decision      | 86 days   |
| Third-party review    | No  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Biotrack, Inc.</b>                   |
| Location       | Sunnyvale, CA, US                       |
| Contact        | JIM ALLEN                               |
| 510(k) history | 16 submissions · 16 cleared · 1986-1993 |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k860719/>; 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 29, 2026