

**K972170 ESR CONTROL-HC HEMATOLOGY ERYTHROCYTE SEDIMENTATION**

Jul 24, 1997  
45 days to decision

K972170 · Product code: **JPK** · Hematology  
Source: <https://www.510kdatabase.net/k972170/>

**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | Mixture, Hematology Quality Control (JPK) |
| Date received         | Jun 9, 1997                               |
| Decision date         | Jul 24, 1997                              |
| Days to decision      | 45 days                                   |
| Third-party review    | No  |
| Summary / Statement   | Summary                                   |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>R&amp;D Systems, Inc.</b>            |
| Location       | Mchenry, IL, US                         |
| Contact        | KENNETH EDDS                            |
| 510(k) history | 79 submissions · 79 cleared · 1978-2016 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k972170/>, Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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