

**K951632 ORTHO-MUNE OK-COMBO CONTROL IGG2A-FITC/IGG2A-PE MONOCLONAL ANTIBODY (MURINE)**Mar 6, 1997  
699 days to decisionK951632 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k951632/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Counter, Differential Cell (GKZ)   |
| Date received         | Apr 7, 1995                        |
| Decision date         | Mar 6, 1997                        |
| Days to decision      | 699 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Ortho Diagnostic Systems, Inc.</b>     |
| Location       | Carpinteria, CA, US                       |
| Contact        | JOANNE HARRIS                             |
| 510(k) history | 126 submissions · 126 cleared · 1981-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k951632/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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