

**K946335 OPTICLONE(TM CD3 FITC/CD19 PE MONOCLONAL ANTIBODIES**Oct 20, 1995  
295 days to decisionK946335 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k946335/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Counter, Differential Cell (GKZ)   |
| Date received         | Dec 29, 1994                       |
| Decision date         | Oct 20, 1995                       |
| Days to decision      | 295 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Immunotech, Inc.</b>               |
| Location       | Westbrook, ME, US                     |
| Contact        | JAMES W CHAMPLIN                      |
| 510(k) history | 3 submissions · 3 cleared · 1995-1995 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k946335/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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