

**K885307 FLIPSCREEN (TM) TOTAL E IMMUNOASSAY**Mar 8, 1989  
71 days to decisionK885307 · Product code: **DGC** · Immunology  
Source: <https://www.510kdatabase.net/k885307/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Ige, Antigen, Antiserum, Control (DGC) |
| Date received         | Dec 27, 1988                           |
| Decision date         | Mar 8, 1989                            |
| Days to decision      | 71 days                                |
| Third-party review    | No                                     |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Alerchek, Inc.</b>                 |
| Location       | Portland, ME, US                      |
| Contact        | WAYNE M HENRY                         |
| 510(k) history | 3 submissions · 3 cleared · 1986-1989 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k885307/>; 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 30, 2026