

**K913130 STRATUS IINTELLECT IMMUNOASSAY SYSTEM**Sep 27, 1991  
73 days to decisionK913130 · Product code: **KHO** · Chemistry  
Source: <https://www.510kdatabase.net/k913130/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | Fluorometer, For Clinical Use (KHO) |
| Date received         | Jul 16, 1991                        |
| Decision date         | Sep 27, 1991                        |
| Days to decision      | 73 days                             |
| Third-party review    | No                                  |
| Summary / Statement   | Summary                             |

**APPLICANT**

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|----------------|---|
| Company        | <b>Baxter Healthcare Corp</b>             |
| Location       | Mchenry, IL, US                           |
| Contact        | NANCY A.HORNBAKER                         |
| 510(k) history | 505 submissions · 496 cleared · 1977-2019 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913130/> 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 May 17, 2026