

**K813216 SECURE FDI TEST KIT**Dec 17, 1981  
38 days to decisionK813216 · Product code: **JHG** · Chemistry  
Source: <https://www.510kdatabase.net/k813216/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                             |
| Submission type       | Traditional  |
| Device classification | Chromatographic Separation, Lecithin/sphingomyelin Ratio (JHG) |
| Date received         | Nov 9, 1981  |
| Decision date         | Dec 17, 1981   |
| Days to decision      | 38 days  |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Beckman Instruments, Inc.</b>                              |
| Location       | Mchenry, IL, US   |
| Website        | <a href="https://www.beckman.com">https://www.beckman.com</a> |
| 510(k) history | 281 submissions · 281 cleared · 1976-1998                     |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k813216/>; 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 22, 2026