

**K013323 TCI-31 LIFELONG OVULATION TESTER**Dec 5, 2001  
61 days to decisionK013323 · Product code: **CEP** · Chemistry  
Source: <https://www.510kdatabase.net/k013323/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)          |
| Submission type       | Traditional                                 |
| Device classification | Radioimmunoassay, Luteinizing Hormone (CEP) |
| Date received         | Oct 5, 2001                                 |
| Decision date         | Dec 5, 2001                                 |
| Days to decision      | 61 days                                     |
| Third-party review    | No  |
| Summary / Statement   | Summary                                     |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Tci New York</b>                   |
| Location       | Los Angeles, CA, US                   |
| Contact        | Erika B Ammirati                      |
| 510(k) history | 1 submissions · 1 cleared · 2001-2001 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013323/> 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