

**K970124 LIPASE REAGENT SET (COLIPASE METHOD)**Mar 6, 1997  
51 days to decisionK970124 · Product code: **CET** · Chemistry  
Source: <https://www.510kdatabase.net/k970124/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)               |
| Submission type       | Traditional                                      |
| Device classification | Olive Oil Emulsion (turbidimetric), Lipase (CET) |
| Date received         | Jan 14, 1997                                     |
| Decision date         | Mar 6, 1997                                      |
| Days to decision      | 51 days  |
| Third-party review    | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Teco Diagnostics</b>                 |
| Location       | Placentia, CA, US                       |
| Contact        | ANDREW REAMS                            |
| 510(k) history | 51 submissions · 51 cleared · 1993-2017 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970124/> 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 31, 2026