

**K896329 D-CHEM TOTAL T4 TEST KIT FOR THYROXINE  
QUANTITA.**Dec 12, 1989  
40 days to decisionK896329 · Product code: **KLI** · Chemistry  
Source: <https://www.510kdatabase.net/k896329/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                          |
| Submission type       | Traditional   |
| Device classification | Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI) |
| Date received         | Nov 2, 1989   |
| Decision date         | Dec 12, 1989  |
| Days to decision      | 40 days   |
| Third-party review    | No  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Photec Diagnostics, Inc.</b>         |
| Location       | Little Falls, NJ, US                    |
| Contact        | BARRY MCDONALD                          |
| 510(k) history | 12 submissions · 12 cleared · 1985-1990 |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k896329/>; 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