

**K823034 SYVA ADVANCE THYROXINE ASSAY**Nov 8, 1982  
18 days to decisionK823034 · Product code: **KLI** · Toxicology  
Source: <https://www.510kdatabase.net/k823034/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                          |
| Submission type       | Traditional   |
| Device classification | Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI) |
| Date received         | Oct 21, 1982  |
| Decision date         | Nov 8, 1982   |
| Days to decision      | 18 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |

**APPLICANT**

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| Company        | <b>Syva Co.</b>                           |
| Location       | Mchenry, IL, US                           |
| 510(k) history | 448 submissions · 447 cleared · 1976-2001 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k823034/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026