

K841601 TERUMO SENSIBEAD THYROXINE EIA KITMay 22, 1984
34 days to decisionK841601 · Product code: **KLI** · Chemistry
Source: <https://www.510kdatabase.net/k841601/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI) |
| Date received | Apr 18, 1984 |
| Decision date | May 22, 1984 |
| Days to decision | 34 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Terumo Medical Corp. |
| Location | Elkton, MD, US |
| 510(k) history | 143 submissions · 143 cleared · 1980-2011 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k841601/> Data sourced from FDA 510(k) public records (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. - Generated May 28, 2026