

K881357 EMIT CONVENIENCE PACK: THYROXINE ASSAYMay 27, 1988
57 days to decisionK881357 · Product code: **KLI** · Chemistry
Source: <https://www.510kdatabase.net/k881357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI)
Date received	Mar 31, 1988
Decision date	May 27, 1988
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Syva Co.
Location	Mchenry, IL, US
Contact	ROGERS, JR.
510(k) history	448 submissions · 447 cleared · 1976-2001

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k881357/>. 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 June 18, 2026