

K003414 VARELISA TG (THYROGLOBULIN) ANTIBODIES,Nov 27, 2000
25 days to decisionK003414 · Product code: **JZO** · Immunology
Source: <https://www.510kdatabase.net/k003414/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Nov 2, 2000
Decision date	Nov 27, 2000
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pharmacia & Upjohn Co.
Location	Westerville, OH, US
Contact	KAREN E MATIS
510(k) history	18 submissions · 18 cleared · 1996-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003414/> 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 29, 2026