

K993585 VARELISA TPO ANTIBODIES, MODEL 12348/12396Jan 5, 2000
75 days to decisionK993585 · Product code: **JZO** · Immunology
Source: <https://www.510kdatabase.net/k993585/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Oct 22, 1999
Decision date	Jan 5, 2000
Days to decision	75 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

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