

K984228 IS ANTI-TPO IGG ELISA TEST SYSTEMFeb 2, 1999
69 days to decisionK984228 · Product code: **JZO** · Immunology
Source: <https://www.510kdatabase.net/k984228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Nov 25, 1998
Decision date	Feb 2, 1999
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Columbia Bioscience, Inc.
Location	Frederick, MD, US
Contact	NORMAN JENKINS
510(k) history	13 submissions · 13 cleared · 1996-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k984228/> 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