

K963695 IMMULITE ANTI-TPO-AB(LKTOI,LKT05,LKTOZJan 17, 1997
123 days to decisionK963695 · Product code: **JZO** · Immunology
Source: <https://www.510kdatabase.net/k963695/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Sep 16, 1996
Decision date	Jan 17, 1997
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Diagnostic Products Corp.
Location	Mchenry, IL, US
Contact	EDWARD M LEVINE, PH.D.
510(k) history	321 submissions · 321 cleared · 1976-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963695/> 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 20, 2026