

K905486 IMMUNOWELL TPO (MICROSOME) TESTJan 3, 1991
28 days to decisionK905486 · Product code: **JNL** · Immunology
Source: <https://www.510kdatabase.net/k905486/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunochemical, Thyroglobulin Autoantibody (JNL)
Date received	Dec 6, 1990
Decision date	Jan 3, 1991
Days to decision	28 days
Third-party review	No

APPLICANT

Company	General Biometrics, Inc.
Location	San Diego, CA, US
Contact	BRYAN L KIEHL
510(k) history	23 submissions · 23 cleared · 1989-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k905486/>; 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 30, 2026