

K943580 AUTOSTAT II ANTI-TPOApr 17, 1995
269 days to decisionK943580 · Product code: **JNL** · Immunology
Source: <https://www.510kdatabase.net/k943580/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunochemical, Thyroglobulin Autoantibody (JNL)
Date received	Jul 22, 1994
Decision date	Apr 17, 1995
Days to decision	269 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Cogent Diagnostics , Ltd.
Location	Dunblane, Fk15 9ep, GB
Contact	PETER MCGREGOR
510(k) history	31 submissions · 31 cleared · 1992-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943580/> 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