

K011082 TPO IGG ANTIBODY EIA TESTJun 6, 2001
57 days to decisionK011082 · Product code: **JZO** · Immunology
Source: <https://www.510kdatabase.net/k011082/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Apr 10, 2001
Decision date	Jun 6, 2001
Days to decision	57 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Scimedx Corp.
Location	Denvill, NJ, US
Contact	Gary Lehnus
510(k) history	14 submissions · 14 cleared · 1996-2001

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