

K951320 AURAFLEX TG-AB AND TPO-ABAug 25, 1995
155 days to decisionK951320 · Product code: **JNL** · Immunology
Source: <https://www.510kdatabase.net/k951320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunochemical, Thyroglobulin Autoantibody (JNL)
Date received	Mar 23, 1995
Decision date	Aug 25, 1995
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Organon Teknika Corp.
Location	Mchenry, IL, US
Contact	C. D KAFADER II
510(k) history	130 submissions · 129 cleared · 1980-2000

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