FDA 510(k) Premarket Notification

K011201 ALPCO MILENIA ANTI-TPO ELISA

CLEARED

May 24, 2001
35 days to decision

K011201 · Product code: **JZO** · Immunology
Source: https://www.510kdatabase.net/k011201/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Apr 19, 2001
Decision date	May 24, 2001
Days to decision	35 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**American Laboratory Products Co., Ltd.**
Location	Windham, NH, US
Contact	RICHARD E CONLEY
510(k) history	27 submissions · 27 cleared · 1991-2002

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k011201/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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