

K090760 THERATEST EL-ANTI-TPO AND THERATEST EL-ANTI-THYROGLOBULIN, MODEL 104-119, 103-120

Sep 3, 2009
164 days to decision

K090760 · Product code: **JZO** · Immunology
Source: <https://www.510kdatabase.net/k090760/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Mar 23, 2009
Decision date	Sep 3, 2009
Days to decision	164 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Theratest Laboratories, Inc.
Location	Chicago, IL, US
Contact	GABRIELLA LAKOS
510(k) history	22 submissions · 22 cleared · 1991-2010

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k090760/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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