

K092229 THYRETAIN TM TSI REPORTER BIOASSAYMay 18, 2010
299 days to decisionK092229 · Product code: **JZO** · Immunology
Source: <https://www.510kdatabase.net/k092229/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Jul 23, 2009
Decision date	May 18, 2010
Days to decision	299 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diagnostic Hybrids, Inc.
Location	Athens, OH, US
Contact	Ronald H Lollar
510(k) history	37 submissions · 36 cleared · 1988-2014

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