

**K083391 THYROID STIMULATING IMMUNOGLOBULIN
REPORTER ASSAY**

May 21, 2009
185 days to decision

K083391 · Product code: **JZO** · Immunology
Source: <https://www.510kdatabase.net/k083391/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Nov 17, 2008
Decision date	May 21, 2009
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k083391/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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