

**K080092 ELECSYS ANTI-TSHR IMMUNOASSAY, ELECSYS  
PRECICONTROL THYROAB**Jul 28, 2008  
196 days to decisionK080092 · Product code: **JZO** · Immunology  
Source: <https://www.510kdatabase.net/k080092/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Jan 14, 2008
Decision date	Jul 28, 2008
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Roche Diagnostics Corp.</b>
Location	Indianapolis, IN, US
Contact	STEPHANIE GREEMAN
510(k) history	264 submissions · 263 cleared · 1999-2013

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080092/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026