

**K193313 Elecsys Anti-TSHR**Feb 27, 2020  
90 days to decisionK193313 · Product code: **JZO** · Immunology  
Source: <https://www.510kdatabase.net/k193313/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Nov 29, 2019
Decision date	Feb 27, 2020
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics</b>
Location	Indianapolis, IN, US
Contact	Reanna Toney
Website	<a href="https://diagnostics.roche.com">https://diagnostics.roche.com</a>
510(k) history	182 submissions · 180 cleared · 2005-2026

Roche Diagnostics is a Swiss multinational healthcare company specializing in diagnostic devices and solutions. The company operates its U.S. diagnostics division from Indianapolis. Roche Diagnostics maintains a strong FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 2005. The company's portfolio spans chemistry devices, immunology assays, microbiology testing, and hematology systems. The latest clearance in 2026 reflects continued innovation and regulatory engagement. Recent cleared devices include glucose monitoring systems, elec...