

**K171731 KRONUS IA-2 Autoantibody (IA-2Ab) ELISA Kit**Jan 19, 2018  
221 days to decisionK171731 · Product code: **OIF** · Chemistry  
Source: <https://www.510kdatabase.net/k171731/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tyrosine Phosphatase (ia-2) Autoantibody Assay (OIF)
Date received	Jun 12, 2017
Decision date	Jan 19, 2018
Days to decision	221 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Kronus, Inc.</b>
Location	Star, ID, US
Contact	Brian Deis
510(k) history	5 submissions · 4 cleared · 2016-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171731/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026