

K220085 KRONUS IA-2 Autoantibody (IA-2Ab) ELISA KitAug 24, 2023
590 days to decisionK220085 · Product code: **OIF** · Chemistry
Source: <https://www.510kdatabase.net/k220085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tyrosine Phosphatase (ia-2) Autoantibody Assay (OIF)
Date received	Jan 11, 2022
Decision date	Aug 24, 2023
Days to decision	590 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Kronus, Inc.
Location	Star, ID, US
Contact	Delaney Sauer
510(k) history	5 submissions · 4 cleared · 2016-2023

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