

K180607 Steroid 21-Hydroxylase Antibody (21-OHAb) ELISA KitNov 23, 2018
261 days to decisionK180607 · Product code: **PCG** · Immunology
Source: <https://www.510kdatabase.net/k180607/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	21-hydroxylase Antibody (21-ohab) (PCG)
Date received	Mar 7, 2018
Decision date	Nov 23, 2018
Days to decision	261 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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