

K182479 NOVEOS Immunoassay Analyzer, NOVEOS Specific IgE (sIgE) Assay, Capture Reagent D001, Dermatophagoides pteronyssinus

Dec 4, 2018
85 days to decision

K182479 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k182479/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Sep 10, 2018
Decision date	Dec 4, 2018
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hycor Biomedical
Location	Garden Grove, CA, US
Contact	Tara Viviani
510(k) history	7 submissions · 7 cleared · 2018-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k182479/> 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 May 25, 2026