

K191510 Noveos Immunoanalyzer System, Noveos Specific IgE (sIgE), Capture Reagent D002, Dermatophagoides farinaeJul 31, 2019
55 days to decisionK191510 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k191510/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Jun 6, 2019
Decision date	Jul 31, 2019
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191510/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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