

K252493 NOVEOS Specific IgE (sIgE)Dec 23, 2025
137 days to decisionK252493 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k252493/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Aug 8, 2025
Decision date	Dec 23, 2025
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Capture Reagent F024, Shrimp (Shrimp spp.); Capture Reagent F207, Clam (Mercenaria mercenaria); Capture Reagent F256, Walnut (Juglans spp.) ; Capture Reagent I006, German Cockroach (Blatella germanica)

APPLICANT

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

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