

K260059 NOVEOS Specific IgE (slgE)May 15, 2026
127 days to decisionK260059 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k260059/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Jan 8, 2026
Decision date	May 15, 2026
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Capture Reagent F018, Brazil Nut (<i>Bertholletia excelsa</i>); Capture Reagent F036, Coconut (<i>Cocos nucifera</i>); Capture Reagent F040, Tuna (<i>Thunnus sp.</i>); Capture Reagent F041, Salmon (<i>Salmo salar</i>); Capture Reagent F075, Egg Yolk (<i>Gallus gallus</i>); Capture Reagent F201, Pecan Nut (<i>Carya illinoensis</i>); Capture Reagent F203, Pistachio Nut (<i>Pistacia vera</i>); Capture Reagent F290, Oyster (<i>Ostrea edulis</i>)

APPLICANT

Company	Hycor Biomedical
Location	Garden Grove, CA, US
Contact	Hiromi Kubota
510(k) history	8 submissions · 8 cleared · 2018-2026

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