

K261027 NOVEOS Specific IgE (sIgE)

Jul 24, 2026
116 days to decision

K261027 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k261027/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Mar 30, 2026
Decision date	Jul 24, 2026
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary
Other names	Capture Reagent F014, Soybean (Glycine max); Capture Reagent F017, Hazelnut (Corylus avellana); Capture Reagent F352, Ara h 8 PR-10, Peanut; Capture Reagent F423, Ara h 2, Peanut; Capture Reagent F447, Ara h 6, Peanut

APPLICANT

Company	Hycor Biomedical
Location	Garden Grove, CA, US
Contact	Aashrey Kaul
510(k) history	11 submissions · 11 cleared · 2018-2026