

K260591 NOVEOS Specific IgE (sIgE)

Jul 21, 2026
148 days to decision

K260591 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k260591/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Feb 23, 2026
Decision date	Jul 21, 2026
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary
Other names	Capture Reagent F010, Sesame Seed (Sesamum indicum);Capture Reagent F020, Almond (Amygdalus communis);Capture Reagent F078, Bos d 8 Casein, Milk; Capture Reagent F080, Lobster (Homarus gammarus);Capture Reagent F422, Ara h 1, Peanut

APPLICANT

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