

K260280 NOVEOS Specific IgE (slgE)Jun 18, 2026
140 days to decisionK260280 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k260280/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Radioallergosorbent (rast) Immunological (DHB) |
| Date received | Jan 29, 2026 |
| Decision date | Jun 18, 2026 |
| Days to decision | 140 days |
| Third-party review | No |
| Summary / Statement | Summary |
| Other names | Capture Reagent F004, Wheat (<i>Triticum aestivum</i>); Capture Reagent F023, Crab (<i>Callinectes</i> spp.); Capture Reagent F079, Gluten, Wheat; Capture Reagent F202, Cashew Nut (<i>Anacardium occidentale</i>); Capture Reagent F233, Gal d 1 Ovomucoid Egg |

APPLICANT

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|----------------|---------------------------------------|
| Company | Hycor Biomedical |
| Location | Garden Grove, CA, US |
| Contact | Aashrey Kaul |
| 510(k) history | 9 submissions · 9 cleared · 2018-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260280/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 11, 2026