

**K200825 NOVEOS Specific IgE (sIgE), Capture Reagent Cat Dander - E001, Felis Domesticus**Jun 26, 2020  
88 days to decisionK200825 · Product code: **DHB** · Immunology  
Source: <https://www.510kdatabase.net/k200825/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Mar 30, 2020
Decision date	Jun 26, 2020
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary
Other names	NOVEOS Specific IgE (sIgE), Capture Reagent Timothy Grass- G006, Phleum pratense

**APPLICANT**

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Company	<b>Hycor Biomedical</b>
Location	Garden Grove, CA, US
Contact	Irene M. Guzman
510(k) history	7 submissions · 7 cleared · 2018-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200825/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026