June 18, 2026

Hycor Biomedical
Aashrey Kaul
Regulatory Affairs and Quality Assurance Manager
7272 Chapman Ave.
Garden Grove, California 92841

Re: K260280
Trade/Device Name: NOVEOS Specific IgE (sIgE)
Capture Reagent F004, Wheat (Triticum aestivum);
Capture Reagent F023, Crab (Callinectes spp.);
Capture Reagent F079, Gluten, Wheat;
Capture Reagent F202, Cashew Nut (Anacardium occidentale);
Capture Reagent F233, Gal d 1 Ovomucoid, Egg
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) immunological test system
Regulatory Class: Class II
Product Code: DHB
Dated: May 16, 2026
Received: May 18, 2026

Dear Aashrey Kaul:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn

(https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260280

Device Name
NOVEOS Specific IgE (sIgE);
Capture Reagent F004, Wheat (Triticum aestivum);
Capture Reagent F023, Crab (Callinectes spp.);
Capture Reagent F079, Gluten, Wheat;
Capture Reagent F202, Cashew Nut (Anacardium occidentale);
Capture Reagent F233, Gal d 1 Ovomucoid, Egg

Indications for Use *(Describe)*
The NOVEOS™ Specific IgE Assay is an in vitro quantitative assay for the measurement of allergen specific IgE in human serum. NOVEOS Specific IgE Assay is to be used with the NOVEOS Immunoassay Analyzer. It is intended for use as an in vitro diagnostic aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings and is to be used in clinical laboratories.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

NOVEOS® Specific IgE

This 510(k) summary is prepared in accordance with the requirements of 21 CFR Part 807.92.

Date of Preparation: 16th May 2026

Manufacturer: Hycor Biomedical, LLC
7272 Chapman Avenue
Garden Grove, CA 92841

Contact Person: Aashrey Kaul
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Garden Grove, CA 92841
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Device Name:

NOVEOS® Specific IgE (sIgE)
Capture Reagent F004, Wheat (Triticum aestivum);
Capture Reagent F023, Crab (Callinectes spp.);
Capture Reagent F079, Gluten, Wheat;
Capture Reagent F202, Cashew Nut (Anacardium occidentale);
Capture Reagent F233, Gal d 1 Ovomucoid, Egg

Classification

NOVEOS® Specific IgE (sIgE)

Product Code: DHB
Class: II
CFR § 866.5750

Substantial Equivalence to: K051218

ImmunoCAP Specific IgE

ImmunoCAP Allergens f4, f23, f79, f202, and f233

Indications for Use/ Intended Use

The NOVEOS™ Specific IgE assay is an *in vitro* quantitative assay for the measurement of allergen specific IgE in human serum. NOVEOS Specific IgE assay is to be used with the NOVEOS Immunoassay Analyzer. It is intended for use as an *in vitro* diagnostic aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings and is to be used in clinical laboratories.

General Description

Reagents

The IgE common reagents include: Diluent A, Conjugate IgE, Substrate A, Substrate B, and Fluo Beads™. Other required and recommended reagents include the allergen specific Capture Reagent, IgE Calibrator Set (6 levels (kU/L) - Cal 0.07 IgE, Cal 0.35 IgE, Cal 0.70 IgE, Cal 3.5 IgE, Cal 17.5 IgE, Cal 100 IgE), Calibrator Antibody IgE, Probe Wash Pack, Wash Buffer Concentrate, Cuvette Wash Pack, IgE Negative Control Pack, and IgE Positive Control Pack.

Assay Principle

The NOVEOS Specific IgE assay is an immunometric, chemiluminescent procedure for the quantitative determination of IgE of known specificity in human serum samples. It employs fluorescent labelled magnetic, streptavidin coated microparticles which are incubated with a biotinylated allergenic capture reagent, patient sample and monoclonal anti-human IgE antibody: horseradish peroxidase conjugate. If present in the sample, IgE binds to the biotinylated allergen captured to the streptavidin-coated microparticles to form a complex. After a final wash, the resulting complex is incubated with the enzyme substrate and a chemiluminescent signal is generated, the magnitude of which is proportional to the concentration of IgE in the patient sample.

The concentration of allergen-specific IgE is determined from a standard curve, which is traceable to the World Health Organization (WHO) reference reagent serum Immunoglobulin E (IgE) 11/234.

Device Comparison

NOVEOS Specific IgE assay on the NOVEOS Immunoassay Analyzer is comparable to ImmunoCAP Specific IgE on the Phadia 100 or 250 Analyzer. Both are automated immunoassay systems that process all assay steps and automatically generate results. See the table on the next page for a summary comparison of the two systems.

Similarities and Differences		
General Device Characteristic	**NOVEOS Specific IgE**	**ImmunoCAP Specific IgE**
Intended Use	The NOVEOS Specific IgE assay is an *in vitro* quantitative assay for the measurement of allergen specific IgE in human serum. NOVEOS Specific IgE assay is to be used with the NOVEOS Immunoassay Analyzer. It is intended for use as an *in vitro* diagnostic aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings and is to be used in clinical laboratories.	ImmunoCAP Specific IgE is an *in vitro* quantitative assay for the measurement of allergen specific IgE in human serum or plasma (EDTA or Na-Heparin). ImmunoCAP Specific IgE is to be used with instruments Phadia 100, Phadia 250, Phadia 1000, Phadia 2500 and Phadia 5000. It is intended for *in vitro* diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories.
Specimen Type	Serum	Serum or plasma (EDTA, Na Heparin)
Sample Volume	4 µL	40 µL
Assay Type	Quantitative	Same
Detection Antibody	Horseradish peroxidase conjugated mouse anti-human IgE monoclonal antibody	β-Galactosidase-anti-human IgE (mouse monoclonal antibody)
Detection Limit	F004, Wheat: LoB: 0.07 kU/L LoD: 0.10 kU/L LoQ: 0.10 kU/L F023, Crab: LoB: 0.07 kU/L LoD: 0.09 kU/L LoQ: 0.10 kU/L F079, Gluten, Wheat: LoB: 0.07 kU/L LoD: 0.08 kU/L	LoB: 0.001 kU/L LoD: 0.02 kU/L LoQ: 0.10 kU/L

	LoQ: 0.10 kU/L F202, Cashew Nut: LoB: 0.07 kU/L LoD: 0.09 kU/L LoQ: 0.10 kU/L F233, Gal d 1 Ovomucoid, Egg: LoB: 0.07 kU/L LoD: 0.09 kU/L LoQ: 0.10 kU/L	
Laboratory Setting	Clinical Laboratory	Same
Assay Principles	Fluorescence adjusted, immunometric, chemiluminescent assay	Fluoroenzyme-immunoassay
Solid Phase	Magnetic microparticles	Cellulose derivative
Calibrator Traceability	World Health Organization (WHO) reference reagent serum Immunoglobulin E (IgE) 11/234	Same
Calibration Method	Heterologous interpolation based on Total IgE calibration curve	Same
Stored Calibration Curve	Yes, up to 28 days	Same
Number of Calibrators	Six	Same
Calibrator Levels	Six levels at 0.07, 0.35, 0.7, 3.5, 17.5 and 100 kU/L	Six levels at 0, 0.35, 0.7, 3.5, 17.5 and 100 kU/L
Assay Range	F004, Wheat: 0.10 – 100 kU/L F023, Crab: 0.10 – 100 kU/L F079, Gluten, Wheat: 0.10 – 100 kU/L F202, Cashew Nut: 0.10 – 100 kU/L	Same

	F233, Gal d 1 Ovomucoid, Egg: 0.10 – 100 kU/L	
Reaction Temperature	37°C	Same
Instrument(s)	NOVEOS Immunoassay Analyzer	Phadia 100, Phadia 250/1000/2500/5000
Time to First Result	1 hour 45 minutes	1 hour 45 minutes to 2 hour 30 minutes depending on model

Clinical Performance

A clinical study that compares NOVEOS sIgE allergen results to the allergic status of 160 to 180 patients was performed to support the diagnostic performance of the NOVEOS sIgE allergens F004 (Wheat), F023 (Crab), F079 (Gluten, Wheat), F202 (Cashew Nut), and F233 (Gal d 1 Ovomucoid, Egg). A total of 34 to 53 samples with allergic status (atopic) was confirmed by oral food challenge or physician diagnosis, and the other 120 to 127 samples were deemed negative (non-atopic) by ImmunoCAP testing (result <0.35 kU/L).

Results are expressed as positive when a sample has an sIgE value greater than or equal to 0.35 kU/L, and negative when a sample has an sIgE value is less than 0.35 kU/L. Clinical sensitivity and specificity for each allergen under evaluation are summarized in the following table:

NOVEOS sIgE Allergens		Clinical Diagnosis		
		Atopic	Non-Atopic	Total
F004, Wheat	Positive	44	0	44
	Negative	4	124	128
	Total	48	124	172
	Clinical sensitivity: 91.7% (95% CI 80.4% to 96.7%) Clinical specificity: 100.0% (95% CI 97.0% to 100.0%)			
F023, Crab	Positive	38	0	38
	Negative	9	120	129
	Total	47	120	167
	Clinical sensitivity: 80.9% (95% CI 67.5 % to 89.6 %) Clinical specificity: 100.0% (95% CI 96.9% to 100.0%)			
F079, Gluten, Wheat	Positive	37	0	37
	Negative	7	126	133
	Total	44	126	170
	Clinical sensitivity: 84.1% (95% CI 70.6% to 92.1%) Clinical specificity: 100.0% (95% CI 97.0% to 100.0%)			
F202, Cashew Nut	Positive	52	0	52
	Negative	1	127	128
	Total	53	127	180
	Clinical sensitivity: 98.1% (95% CI 90.1% to 99.7%) Clinical specificity: 100.0% (95% CI 97.1% to 100.0%)			
F233, Gal d 1 Ovomucoid, Egg	Positive	24	0	24
	Negative	10	126	136
	Total	34	126	160
	Clinical sensitivity: 70.6% (95% CI 53.8% to 83.2%) Clinical specificity: 100.0% (95% CI 97.0% to 100.0%)			

The following literature was published that supports the observed sensitivity of the NOVEOS sIgE assay F233 allergens.

NOVEOS sIgE assay	Literature Citation(s)	Prevalence	Reported Performance
F233, Gal d 1 Ovomucoid, Egg Sensitivity: 70.6% Specificity: 100.0%	Gupta RS, et al. JAMA Network Open. 2019;2(1):e185630	0.8% egg allergy among US adults	not reported
	Bartnikas LM, et al. J Allergy Clin Immunol Pract. 2013;1(4):354-360.	n/a	Sensitivity: 66.7% Specificity: 61.3%

Precision/Reproducibility

Repeatability and within-laboratory precision of NOVEOS sIgE allergens were determined in accordance with CLSI guideline EP05-A3: *Evaluation of Precision of Quantitative Measurement Procedures – 3rd Edition* and CLSI guideline EP15-A3: *User Verification of Precision and Estimation of Bias – 3rdEdition.* A panel of four to five samples (two negative and two to three positive patient samples) was assayed in at least duplicate for two runs per day, over at least 20 days, on one to two NOVEOS Immunoassay Analyzers for a total of at least 80 replicates per sample. One lot of NOVEOS sIgE allergens was used for testing each sample.

The SD and % CV of the within- run, between-run, between-day, and total imprecision were calculated for each sample and results are summarized in the following table:

Sample	N	Mean (kU/L)	Within-Run (Repeatability)		Between-Run		Between-Day		Total	
			SD	CV	SD	CV	SD	CV	SD	CV
NOVEOS F004, Wheat										
1	80	0.12	0.02	12.8%	0.01	9.0%	0.01	9.6%	0.02	18.3%
2	80	0.30	0.02	5.8%	0.02	5.1%	0.01	2.6%	0.02	8.2%
3	80	2.68	0.11	4.1%	0.00	0.0%	0.07	2.5%	0.13	4.8%
4	80	74.79	4.63	6.2%	0.00	0.0%	4.09	5.5%	6.18	8.3%
NOVEOS F023, Crab										
1	80	0.14	0.01	7.1%	0.01	7.0%	0.01	8.1%	0.02	12.9%
2	80	0.34	0.02	7.2%	0.00	0.0%	0.02	4.7%	0.03	8.6%
3	80	2.53	0.08	3.1%	0.06	2.4%	0.00	0.0%	0.10	4.0%
4	80	88.26	3.94	4.5%	2.52	2.9%	2.27	2.6%	5.20	5.9%
NOVEOS F079, Gluten, Wheat										
1	80	0.20	0.01	6.4%	0.00	0.0%	0.02	9.5%	0.02	11.5%
2	80	0.32	0.02	5.8%	0.01	3.3%	0.01	2.7%	0.02	7.2%
3	80	3.20	0.10	3.1%	0.07	2.1%	0.13	4.0%	0.17	5.5%
4	92*	79.21	5.16	6.5%	8.47	10.7%	0.00	0.0%	9.92	12.5%

*Sample 4 was tested with 5 replicates/1st run x 2 replicates/2nd run x 5 days and 2 replicates x 2 runs x 15 days and 3 total replicates dropped

Sample	N	Mean (kU/L)	Within-Run (Repeatability)		Between-Run		Between-Day		Total	
			SD	CV	SD	CV	SD	CV	SD	CV
NOVEOS F202, Cashew Nut										
1	80	0.15	0.01	9.7%	0.00	0.0%	0.01	8.6%	0.02	12.9%
2	80	0.27	0.01	3.8%	0.01	5.2%	0.02	7.3%	0.03	9.7%
3	80	1.24	0.04	2.8%	0.05	3.6%	0.02	1.8%	0.06	5.0%
4	80	5.40	0.30	5.6%	0.08	1.5%	0.12	2.2%	0.34	6.2%
5	95*	86.68	5.86	6.8%	7.19	8.3%	7.70	8.9%	12.05	13.9%
*Sample 5 was tested with 5 replicates/1st run x 2 replicates/2nd run x 5 days and 2 replicates x 2 runs x 15 days										
NOVEOS F233, Gal d 1 Ovomucoid, Egg										
1	80	0.18	0.02	10.7%	0.00	0.0%	0.02	11.4%	0.03	15.7%
2	80	0.27	0.02	5.7%	0.00	1.3%	0.01	4.6%	0.02	7.4%
3	80	1.71	0.10	5.9%	0.00	0.0%	0.08	4.5%	0.13	7.5%
4	95*	93.31	6.16	6.6%	2.11	2.3%	1.82	1.9%	6.76	7.2%
*Sample 4 was tested with 5 replicates/1st run x 2 replicates/2nd run x 5 days and 2 replicates x 2 runs x 15 days										

Lot-to-lot imprecision

Lot-to-lot imprecision was evaluated using a panel of four to five serum samples tested with three different lots of each NOVEOS sIgE allergen. For NOVEOS sIgE allergens F004 (Wheat), F023 (Crab), F079 (Gluten, Wheat), F202 (Cashew Nut), and F233 (Gal d 1 Ovomucoid, Egg) the samples were tested in replicates of five for one run per day, over at least 5 days, for a total of at least 75 replicates per sample. The results are summarized in the following table:

Sample	N	Mean (kU/L)	Within-Run (Repeatability)		Between-Day		Between-Lot		Total	
			SD	CV	SD	CV	SD	CV	SD	CV
NOVEOS F004, Wheat										
1	75	0.13	0.01	9.4%	0.01	9.6%	0.00	0.0%	0.02	13.4%
2	75	0.41	0.02	5.1%	0.00	0.0%	0.01	1.6%	0.02	5.3%
3	75	0.56	0.02	3.9%	0.04	7.3%	0.00	0.6%	0.05	8.3%
4	75	2.94	0.07	2.5%	0.10	3.4%	0.00	0.0%	0.12	4.2%
5	75	77.46	2.96	3.8%	6.53	8.4%	0.00	0.0%	7.17	9.3%

Sample	N	Mean (kU/L)	Within-Run (Repeatability)		Between-Day		Between-Lot		Total	
			SD	CV	SD	CV	SD	CV	SD	CV
NOVEOS F023, Crab										
1	79*	0.14	0.01	8.4%	0.01	5.8%	0.01	6.9%	0.02	12.3%
2	75	0.42	0.02	3.9%	0.02	4.4%	0.00	0.8%	0.03	5.9%
3	75	2.35	0.08	3.4%	0.04	1.7%	0.05	2.2%	0.10	4.4%
4	75	81.20	3.77	4.6%	3.42	4.2%	1.48	1.8%	5.30	6.5%
*Sample 1 was tested with 5 replicates/run x 6 days with exclusion of 1 outlier for Day 2										
NOVEOS F079, Gluten, Wheat										
1	75	0.27	0.02	7.6%	0.00	1.5%	0.00	0.2%	0.02	7.7%
2	75	0.62	0.03	4.4%	0.06	9.2%	0.00	0.0%	0.06	10.2%
3	75	3.09	0.14	4.5%	0.19	6.1%	0.00	0.0%	0.23	7.6%
4	75	77.20	5.14	6.7%	7.66	9.9%	0.00	0.0%	9.22	11.9%
NOVEOS F202, Cashew Nut										
1	75	0.15	0.01	6.5%	0.01	5.1%	0.00	0.0%	0.01	8.2%
2	75	0.45	0.02	4.8%	0.02	5.6%	0.00	0.0%	0.03	7.3%
3	75	1.22	0.03	2.6%	0.08	6.7%	0.00	0.0%	0.09	7.2%
4	75	5.06	0.17	3.4%	0.14	2.8%	0.00	0.0%	0.22	4.4%
5	75	80.36	5.73	7.1%	3.53	4.4%	0.00	0.0%	6.73	8.4%
NOVEOS F233, Gal d 1 Ovomucoid, Egg										
1	75	0.19	0.02	8.3%	0.01	5.5%	0.00	1.4%	0.02	10.1%
2	75	0.47	0.02	3.9%	0.01	2.9%	0.00	0.2%	0.02	4.9%
3	75	1.59	0.07	4.1%	0.06	3.8%	0.00	0.0%	0.09	5.6%
4	75	94.98	7.76	8.2%	1.99	2.1%	0.00	0.0%	8.01	8.4%

Linearity

Linearity of NOVEOS sIgE allergens was evaluated in accordance with CLSI guideline I/LA20-3rd Edition*, Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities*. Three sets of linearity dilution panels consisting of three neat positive human serum samples (low, mid, and high) were used for testing. One negative sample below the assay detection limit was used as the diluent. Each sample was serially diluted to create the full dilution panel. Testing was performed using one lot of each NOVEOS sIgE allergen. The linear regression statistics calculated using the weighted least squares with intercept analysis per CLSI guideline EP06-2nd Edition, *Evaluation of Linearity of Quantitative Measurement Procedures*, are shown in the following tables.

NOVEOS Specific IgE, F004, Wheat				
Dilution Series	**Dilution Range (kU/L)**	**Slope (95% CI)**	**Intercept (95% CI)**	**R^2**
1	0.09 to 5.02	0.97 (0.94 to 0.99)	-0.02 (-0.02 to -0.01)	0.999
2	0.59 to 40.15	1.00 (0.97 to 1.02)	-0.01 (-0.10 to -0.04)	1.000
3	15.14 to 101.30	1.00 (0.96 to 1.04)	-2.88 (-4.04 to -1.72)	0.999
All	**0.09 to 101.30**	**0.96 (0.94 to 0.98)**	**-0.02 (-0.02 to -0.01)**	**0.998**

NOVEOS Specific IgE, F023, Crab				
Dilution Series	**Dilution Range (kU/L)**	**Slope (95% CI)**	**Intercept (95% CI)**	**R^2**
1	0.09 to 2.59	1.02 (0.96 to 1.08)	0.01 (-0.01 to 0.03)	0.997
2	0.92 to 57.67	0.94 (0.88 to 1.00)	0.02 (-0.15 to 0.19)	0.997
3	1.34 to 103.71	0.85 (0.79 to 0.91)	-0.19 (-0.48 to 0.10)	0.996
All	**0.09 to 103.71**	**0.92 (0.88 to 0.95)**	**0.03 (-0.00 to 0.05)**	**0.992**

NOVEOS Specific IgE, F079, Gluten, Wheat				
Dilution Series	**Dilution Range (kU/L)**	**Slope (95% CI)**	**Intercept (95% CI)**	**R^2**
1	0.06 to 1.41	0.98 (0.91 to 1.05)	-0.02 (-0.03 to -0.01)	0.997
2	1.21 to 80.39	0.92 (0.87 to 0.96)	-0.01 (-0.19 to 0.16)	0.998
3	1.54 to 108.94	1.03 (0.94 to 1.11)	-0.44 (-0.75 to -0.12)	0.995
All	**0.06 to 108.94**	**0.92 (0.89 to 0.95)**	**-0.02 (-0.05 to 0.01)**	**0.997**

NOVEOS Specific IgE, F202, Cashew Nut				
Dilution Series	**Dilution Range (kU/L)**	**Slope (95% CI)**	**Intercept (95% CI)**	**R^2**
1	0.08 to 4.03	1.01 (0.99 to 1.04)	0.00 (-0.01 to 0.01)	0.999
2	0.68 to 52.43	0.96 (0.93 to 1.00)	-0.18 (-0.25 to -0.11)	0.999
3	1.67 to 110.21	0.95 (0.90 to 0.99)	0.02 (-0.11 to 0.14)	0.998
All	**0.08 to 110.21**	**0.94 (0.90 to 0.97)**	**0.01 (-0.01 to 0.03)**	**0.994**

NOVEOS Specific IgE, F233, Gal d 1 Ovomucoid, Egg				
Dilution Series	**Dilution Range (kU/L)**	**Slope (95% CI)**	**Intercept (95% CI)**	**R^2**
1	0.08 to 3.00	1.01 (0.96 to 1.06)	-0.02 (-0.04 to -0.01)	0.999
2	0.90 to 47.42	1.10 (1.02 to 1.18)	0.04 (-0.15 to 0.24)	0.996
3	20.86 to 118.50	0.99 (0.91 to 1.07)	-0.18 (-2.47 to 2.11)	0.995
All	**0.08 to 118.50**	**1.08 (1.05 to 1.12)**	**-0.03 (-0.05 to -0.01)**	**0.996**

Endogenous Substance Interference

Interference testing by endogenous substances of NOVEOS sIgE allergens was carried out in accordance with CLSI guideline EP07, *Interference Testing in Clinical Chemistry – Third Edition*. The effect of the presence of elevated levels of human serum albumin, hemoglobin, triglyceride, conjugated bilirubin, and unconjugated bilirubin in serum samples was evaluated by testing three serum sample pools (one negative, one near the cut-off, and one positive) spiked with varying levels of each interferent. To mimic the dilution effect caused by the spiked interferent, the same amount of respective solvent was spiked into each of the sample pools and tested as control samples.

For NOVEOS sIgE allergens F004 (Wheat), F023 (Crab), F079 (Gluten, Wheat), F202 (Cashew Nut), and F233 (Gal d 1 Ovomucoid, Egg) the samples were tested in replicates of seven in one assay run with one lot of Capture Reagent.

The % recovery for each sample spiked with the potential interfering substance was calculated by comparing its result to that of the corresponding control sample. The substances listed in the table below show no significant interference at the indicated test concentrations for all allergens under evaluation.

Substance	Concentration
Hemoglobin	200 mg/dL
Conjugated Bilirubin	30 mg/dL
Unconjugated Bilirubin	20 mg/dL
Intralipid	3000 mg/dL
Human Serum Albumin	121 g/L

Interference testing with rheumatoid factor (RF) was previously performed for NOVEOS sIgE allergens and found no significant interference at 513 IU/mL. For RF interference testing, refer to cleared 510(k) submission K200825.

Exogenous Substance Interference

Interference testing with potentially interfering exogenous substances biotin, diphenhydramine, methylprednisolone, ranitidine, and omalizumab was previously performed for NOVEOS sIgE allergens and found no significant interference at the concentrations listed in the table below. Refer to previously cleared 510(k) submission K200825.

Substance	Concentration
Biotin	3500 ng/mL
Diphenhydramine	19.5 µmol/L
Methylprednisolone	1000 ng/mL
Ranitidine	19.1 µmol/L
Omalizumab	0.12 mg/mL

Cross-Reactivity

Cross-reactivity testing with other human immunoglobulins (IgA, IgD, IgG, and IgM) was previously performed for NOVEOS sIgE allergens that utilize the same universal anti-IgE conjugate reagent as those currently under evaluation and found no significant interference at physiological concentrations of IgA, IgG, IgM (14.86 mg/mL), and IgG (0.173 mg/mL). Refer to previously cleared 510(k) submission K200825.

Competitive Inhibition (Analytical Specificity)

Immunological specificity of NOVEOS sIgE allergens was demonstrated through competitive inhibition in accordance with CLSI I/LA20-3rd Edition, *Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities*.

For each NOVEOS sIgE allergen, a positive sample was tested with specific IgE concentrations shown in the table below:

NOVEOS sIgE Allergen	Concentration (kU/L)
F004, Wheat	2.14
F023, Crab	4.37
F079, Gluten, Wheat	12.70
F202, Cashew Nut	4.46
F233, Gal d 1 Ovomucoid, Egg	2.42

The allergen solution (inhibitor) was diluted 1:1 into the positive sample and subsequently serially diluted five times in two-fold increments. Each diluted sample was evaluated for dose-dependent inhibition in replicates of at least four using one lot of NOVEOS sIgE allergens F004 (Wheat), F023 (Crab), F079 (Gluten, Wheat), F202 (Cashew Nut), and F233 (Gal d 1 Ovomucoid, Egg).

Related and unrelated allergen inhibitors were tested for each NOVEOS sIgE allergen in a single-dose competitive inhibition study. The related and unrelated allergen inhibitors were tested at a concentration at least 10 times the final concentration that achieved >50% inhibition for the allergen under evaluation. The related and unrelated allergens used for each NOVEOS sIgE allergen are shown in the table below:

NOVEOS sIgE Allergen	Related Inhibitor	Unrelated Inhibitors
F004, Wheat	F040, Yellowfin Tuna	• G001, Grass Pollen Sweet Vernal • K082, Latex • T218, Virginia Live Oak Pollen

NOVEOS sIgE Allergen	Related Inhibitor	Unrelated Inhibitors
F023, Crab	F003, Atlantic Cod	• E003, Horse Epithelia • K082, Latex • M006, *Alternaria alternata*
F079, Gluten, Wheat	F076, Bos d 4, α-lactalbumin, Milk	• E221, Can f 3 Dog, Serum Albumin, Dog • M220, Asp f 3, *A. fumigatus* • T215, Bet v 1 PR-10, Birch
F202, Cashew Nut	F040, Yellowfin Tuna	• D201, *Blomia tropicalis* • E070, Goose Feathers/Skin • M012, *Aureobasidium pullulans*
F233, Gal d 1 Ovomucoid, Egg	F076, Bos d 4, α-lactalbumin, Milk	• E221, Can f 3, Dog Serum Albumin, Dog • M218, Asp f 1, *A. fumigatus* • T215, Bet v 1 PR-10, Birch

Inhibitor concentrations used for testing of the NOVEOS sIgE allergens are shown in the table below:

NOVEOS sIgE Allergen	Dose-Dependent Inhibition		Single-Dose Inhibition	
	Highest Tested Inhibitor Conc. (µg/mL)	Final Conc. at >50% Inhibition (µg/mL)	Final Conc. of Related Inhibitor (µg/mL)	Final Conc. of Unrelated Inhibitors (µg/mL)
F004, Wheat	50	12.5	1335	970 - 1325
F023, Crab	50	1.5625	550	510 - 975
F079, Gluten, Wheat	100	100	1460	1200 - 1970
F202, Cashew Nut	100	3.125	1000	1000
F233, Gal d 1 Ovomucoid, Egg	3.125	0.098	31.25	31.25

Greater than 50% inhibition was achieved in the dose-dependent inhibition studies and no inhibition was observed for the related and unrelated inhibitors for all NOVEOS sIgE allergens. The inhibition studies indicate that the NOVEOS sIgE allergens contain their respective immunologically relevant allergens.

Detection Limit

Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) of NOVEOS sIgE allergens were estimated in accordance with CLSI guideline EP17-A2, *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition*.

Limit of Blank

For F004 (Wheat), F023 (Crab), F079 (Gluten, Wheat), F202 (Cashew Nut), and F233 (Gal d 1 Ovomucoid, Egg) the study was done using two lots of capture reagent and one NOVEOS Immunoassay Analyzer. Four analyte-free human serum samples were tested in replicates of five per run, over at least three runs, with no more than one run per day, for at least 60 replicates per lot. The value at the 95th percentile of the total measurements for each of the lots tested was estimated.

Limit of Detection

LoD for each assay was determined by testing multiple human serum samples with low IgE concentrations using two lots of capture reagents and one NOVEOS Immunoassay Analyzer. The LoD was calculated for each lot using parametric analysis. The study protocol is summarized in the table below:

NOVEOS sIgE assay	No. of Samples	No. of Lots	No. of Analyzers	Testing Protocol
F004	5	2	1	5 samples x 5 replicates/run x 3 runs = 75/Lot
F023	4	2	1	4 samples x 5 replicates/run x 3 runs = 60/Lot
F079	4	2	1	4 samples x 5 replicates/run x 3 runs = 60/Lot
F202	5	2	1	5 samples x 5 replicates/run x 3 or 5 runs = 95/Lot* **Two samples had two additional runs.*
F233	4	2	1	4 samples x 5 replicates/run x 3 runs = 60/Lot

Limit of Quantitation

LoQ was evaluated as a functional sensitivity-based approach with no bias component to LoQ. Functional sensitivity for NOVEOS sIgE allergens F004 (Wheat), F023 (Crab), F079 (Gluten, Wheat), F202 (Cashew Nut), and F233 (Gal d 1 Ovomucoid, Egg) was determined using a set of at least four samples with low IgE concentrations and two lots of NOVEOS sIgE allergen. The samples were tested with at least three replicates, over at least three testing days resulting in a total of at least 36 replicates. Data analysis was performed according to the precision profile method using within- lab precision results. The LoQ is defined as the mean value of the lowest sample or by calculating the mean dose at 20%CV which fulfills the specification for the total within-laboratory imprecision (<20%CV).

The claimed LoB, LoD, and LoQ are based on the highest value obtained from the lots tested and are summarized in the table below:

NOVEOS sIgE Allergen	LoB (kU/L)	LoD (kU/L)	LoQ (kU/L)
F004, Wheat	0.07	0.10	0.10
F023, Crab	0.07	0.09	0.10
F079, Gluten, Wheat	0.07	0.08	0.10
F202, Cashew Nut	0.07	0.09	0.10
F233, Gal d 1 Ovomucoid, Egg	0.07	0.09	0.10

Reference Range

The expected value is negative (<0.35 kU/L) for a specific allergen in a non-atopic person. Each laboratory should establish its own expected value.

The expected value/reference range of NOVEOS sIgE assays for F004 (Wheat), F023 (Crab), F079 (Gluten, Wheat), F202 (Cashew Nut), and F233 (Gal d 1 Ovomucoid, Egg) in a normal population was verified in accordance with CLSI EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory – 3rd Edition.

The 95% reference range was calculated by ordering the dose recoveries from 120 to 127 non-atopic samples in ascending order of concentration and identifying the dose recovery that fell at the 95th percentile rank. The 95% reference range for each allergen under evaluation was below the established NOVEOS sIgE cutoff of 0.35 kU/L.

Stability

Shelf-Life Stability

Both an ongoing real-time stability study and an accelerated stability study were performed for NOVEOS sIgE assays for F004 (Wheat), F023 (Crab), F079 (Gluten, Wheat), F202 (Cashew Nut), and F233 (Gal d 1 Ovomucoid, Egg) in accordance with CLSI EP25-Ed2 *Evaluation of Stability of In Vitro Medical Laboratory Test Reagents – Second Edition*. The accelerated stability study and ongoing real-time stability study were performed with two positive and one negative sample using three lots of NOVEOS sIgE allergen (Capture Reagent).

The accelerated stability data supports the manufacturer's claim of unopened shelf-life stability for the capture reagents as listed in the table below. Stability of common assay reagents (reagents except the Capture Reagent) has been established previously in prior submission K182479.

	Shelf-life Stability (2-8°C)
Specific IgE Capture Reagent F004*	36 months
Specific IgE Capture Reagent F023*	36 months
Specific IgE Capture Reagent F079*	36 months
Specific IgE Capture Reagent F202*	36 months
Specific IgE Capture Reagent F233*	36 months

*Based on accelerated stability data

Real-time stability studies of the NOVEOS sIgE allergens are on-going to further support the manufacturer's claim of unopened shelf-life stability when stored at 2-8°C per the manufacturer's instructions for use.

On-Board Stability (OBS)

Real-time OBS stability studies using one lot of NOVEOS sIgE allergens F004 (Wheat), F023 (Crab), F079 (Gluten, Wheat), F202 (Cashew Nut), and F233 (Gal d 1 Ovomucoid, Egg) support the on-board stability claims for capture reagents as summarized in the table below. The real-time on-board stability study was performed with at least 3 samples, including at least two positive samples and one negative or low-level sample using one lot of NOVEOS allergen (Capture Reagent) stored on-board the instrument. OBS of common assay reagents (reagents except the Capture Reagent) has been established previously in prior submission K182479.

	On-board Stability (2-8°C)
Specific IgE Capture Reagent F004	28 days
Specific IgE Capture Reagent F023	28 days
Specific IgE Capture Reagent F079	28 days
Specific IgE Capture Reagent F202	28 days
Specific IgE Capture Reagent F233	28 days

Open-Vial Stability (OVS)

Both an ongoing real-time stability study and an accelerated stability study were performed for the NOVEOS sIgE allergens F004 (Wheat), F023 (Crab), F079 (Gluten, Wheat), F202 (Cashew Nut), and F233 (Gal d 1 Ovomucoid, Egg) in accordance with CLSI EP25-Ed2 *Evaluation of Stability of In Vitro Medical Laboratory Test Reagents – Second Edition*. OVS of common assay reagents (reagents except the Capture Reagent) has been established previously in prior submission K182479. The result supports that the allergen specific capture reagent is stable for 15 days once opened and stored at 2-8°C.

Real-time stability studies of the NOVEOS sIgE allergens are on-going to further support the manufacturer's claim of open-vial shelf-life stability when stored per the manufacturer's instructions for use.

Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.