510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K231151

B Applicant

Kenota Inc.

C Proprietary and Established Names

Kenota 1 Total IgE
Kenota 1 (instrument)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DGC	Class II	21 CFR 866.5510 - Immunoglobulins A, G, M, D, And E Immunological Test System	IM - Immunology

II Submission/Device Overview:

A Purpose for Submission:

New test system

B Measurand:

Human Immunoglobulin E (IgE)

C Type of Test:

Semi-quantitative, fluorescence lateral flow immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Kenota 1 Total IgE is an *in vitro* test system intended for semi-quantitative measurement of total IgE in human capillary whole blood on the Kenota 1 instrument. 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 allergist/immunologist offices.

C Special Conditions for Use Statement(s):

For Prescription Use Only

D Special Instrument Requirements:

Kenota 1

IV Device/System Characteristics:

A Device Description:

The Kenota 1 Total IgE includes the following provided materials and run on Kenota 1 instrument:

1. Kenota 1 Total IgE Cartridge (Two cartridges in a single sealed pouch)
   - Ready for use and for single use
   - Conjugate: Fluorescently labeled anti-human IgE

2. Kenota 1 Total IgE External Controls
   - Two levels (low at 35 kU/L and high at 250 kU/L), each with 300 µL in 1.5 mL microcentrifuge tube
   - Recombinant human IgE-Fc
   - Ready for use and for single use

3. Kenota 1 instrument
   - With a detachable tablet screen
   - Cartridge sleeve loading up to 30 cartridges
   - 25 minutes runtime for the Kenota 1 Total IgE
   - Requires the following components:
     - Kenota 1 Sample Collection Kit intended to be used only for the Kenota 1 Total IgE and consists of syringe assembly, lancet, blood collector (Minivette POCT lithium-

heparin green plunger (100 µL, Sarstedt)), diluent collector (Minivette POCT neutral white plunger (100 µL, Sarstedt)), and diluent

- Kenota 1 Developing Solution (500 mL) contains phosphate buffered saline with stabilizer and preservative, ready for use

The Kenota 1 Total IgE test results are provided in semi-quantitative categories to the ordering allergist/immunologist for interpretation as follows:

Semi-Quantitative Category
Below LoQ* (< 5 kU/L)
Very Low (5–34 kU/L)
Low (35–100 kU/L)
Medium (101–200 kU/L)
High (201–540 kU/L)
Very High (541–900 kU/L)
Above Measuring Range (> 900 kU/L)

*LoQ: Limit of Quantification

B Principle of Operation:

The Kenota 1 Total IgE is a lateral flow immunoassay test system that measures total IgE in human capillary whole blood on the Kenota 1 instrument. After an operator loads the fingerstick (FS) sample into the Kenota 1, the instrument dispenses a set amount of the fingerstick sample (4.5 µL) onto the Kenota 1 Total IgE Cartridge and adds the Kenota 1 Developing Solution to allow the sample to flow along the membrane to the test line containing immobilized mouse anti-human IgE that captures the human IgE in the test sample. This immune complex is captured by mouse anti-(human IgE) IgG bound to the fluorescent reporter. The fluorescent test signal is directly proportional to the level of IgE in the sample. Excess fluorescent reporter conjugates are captured at the control line, which consists of immobilized rat anti-mouse kappa light chain IgG. The Kenota 1 instrument provides a printout of the patient result upon completion of each sample analysis. The operator presents this report to the allergist.

C Instrument Description Information:

1. Instrument Name:

   Kenota 1

2. Specimen Identification:

   Kenota 1 instrument automatically prompts the user to enter the appropriate patient and test request information.

3. Specimen Sampling and Handling:

   The Kenota 1 processes fresh fingerstick whole blood samples collected in a blood collector coated with lithium heparin anticoagulant (Minivette POCT lithium-heparin green plunger

(100 µL, Sarstedt) and transferred to the syringe assembly of the Kenota 1 sample collection kit (SCK) for the Kenota 1 Total IgE. The syringe assembly is manually loaded into the Kenota 1 by the operator.

4. Calibration:

   There is no calibration required to be performed by the end user. Calibration is performed by Kenota, and each lot of cartridges are calibrated by Kenota staff at the manufacturer's site. The calibration of the Kenota 1 Total IgE is directly traceable to the 3rd International Standard for serum IgE (11/234) from the World Health Organization (WHO), using a set of nine working calibrators with values assigned to 0, 2.17, 6.2, 18.6, 37.2, 93, 310, 620, and 930 kU/L.

5. Quality Control:

   Performance of the Kenota 1 Total IgE is verified with the Kenota 1 Total IgE External Controls. The external controls are stabilized control material used for verifying the performance of the Kenota 1 Total IgE and intended users' operational procedures. Results of the external control sessions are not interpreted by the operator but by the Kenota 1 instrument. If both controls fail, the Kenota 1 is automatically locked out and the operator is instructed to contact Kenota Support. The external controls are required to be run when a new lot of Kenota 1 Total IgE cartridge is used, or a new operator is qualified, or when a monthly (every 30 days) maintenance session is performed.

V Substantial Equivalence Information:

A Predicate Device Name(s):

ImmunoCAP Total IgE

B Predicate 510(k) Number(s):

K161899

C Comparison with Predicate(s):

Device & Predicate Device(s):	Candidate K231151	Predicate K161899
Device Trade Name	Kenota 1 Total IgE	ImmunoCAP Total IgE
General Device Characteristic Similarities		
Intended Use/ Indications For Use	The Kenota 1 Total IgE is an in vitro test system intended for semi-quantitative measurement of total IgE in human capillary whole blood on the Kenota 1 instrument. It is intended for in vitro	ImmunoCAP Total IgE is an in vitro test system for the quantitative measurement of circulating total IgE in human serum and plasma. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of

Device & Predicate Device(s):	Candidate K231151	Predicate K161899
	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 allergist/immunologist offices.	IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories. ImmunoCAP Total IgE is to be used with the instruments Phadia 100, Phadia 250, Phadia 1000, Phadia 2500 or Phadia 5000.
Test Principle	Immunofluorescence assay	Same
Analyte	IgE	Same
Capture Antibody	Mouse anti-human IgE monoclonal antibody	Same
Detection Antibody	Europium labeled mouse anti-human IgE monoclonal antibody	Same
Traceability	3rd International Reference Preparation (IRP) 11/234 of Human Serum IgE from World Health Organization (WHO)	Same
General Device Characteristic Differences		
Measurement Type	Semi-quantitative	Quantitative
Sample Type	Fingerstick whole blood (Lithium-Heparin)	Venous serum or plasma (EDTA or Heparin)
Intended Use Environment	Allergist / immunologist offices with a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver.	Clinical laboratory
Sample Volume	4.5 µL	40 µL
Detection Capability	LoD/LoQ: 5 kU/L	LoD/LoQ: 2 kU/L
Reportable Range	5 – 900 kU/L	2 – 5000 kU/L
Calibration	9-level multipoint calibration is performed at the manufacturing site. Lot specific calibration values are coded on the cartridge barcodes	6-level multipoint calibration is performed externally by the operator
Calibrators	0, 2.17, 6.2, 18.6, 37.2, 93, 310, 620, 930 kU/L	2, 10, 50, 200, 1000, 5000 kU/L
Controls	Two levels: Low and High	Three levels: Low, Medium, High

VI Standards/Guidance Documents Referenced:

The following Clinical and Laboratory Standards Institute (CLSI) guidelines were used:

- CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline —Third Edition
- CLSI EP06-Ed2: Evaluation of Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
- CLSI EP07-Ed3: Interference Testing in Clinical Chemistry
- CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition
- CLSI I/LA-20-Ed3: Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities - Third edition
- CLSI EP25-Ed2: Evaluation of Stability of *In Vitro* Medical Laboratory Test Reagents.
- CLSI EP28-A3c: Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition
- CLSI EP37-Ed1: Supplemental Tables for Interference Testing in Clinical Chemistry

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision of the Kenota 1 Total IgE was evaluated according to CLSI document EP05-A3 and included four studies: (a) Variability of cartridge lots, (b) Variability of Instruments, (c) Repeatability of Fingerstick Whole Blood Samples, and (d) Multi-site Reproducibility.

a. Variability of cartridge lots

The study was performed using three cartridge lots of Kenota 1 Total IgE on a single Kenota 1 instrument using four fresh venous whole blood samples collected in lithium-heparin anticoagulant-coated blood collection tubes. The total IgE for each sample was measured in five replicates for each of three Kenota 1 Total IgE cartridge lots, two times per day for five days by a single trained operator on one Kenota 1 instrument, resulting in a total of 150 replicates per sample. The results are summarized in the tables below:

Sample	N	Mean (kU/L)	Repeatability		Between-Run		Between-Day		Between-Lot		Total	
			SD*	%CV^	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low	150	48.4	6.1	12.6	0.0	0.0	1.6	3.3	7.1	14.6	9.5	19.6
Medium	150	131.0	15.0	11.5	0.0	0.0	4.2	3.2	10.7	8.2	18.9	14.5
High	150	312.1	38.8	12.4	0.0	0.0	0.0	0.0	30.9	9.9	49.6	15.9
Very high	150	803.3	63.1	7.9	0.0	0.0	2.9	0.4	45.3	5.6	77.7	9.7

* SD: standard deviation
^%CV: % coefficient of variation

In addition, the table below provides semi-quantitative analysis over three cartridge lots.

Sample	N	Mean (kU/L)	Kenota 1 Total IgE Result Category (kU/L) (%, n/N)						
			< 5	5–34	35–100	101–200	201–540	541–900	> 900
				Very Low	Low	Medium	High	Very High	
Low	150	48.4	0	4.7 % (7/150)	95.3 % (143/150)	0	0	0	0
Medium	150	131.0	0	0	2.7 % (4/150)	97.3 % (146/150)	0	0	0
High	150	312.1	0	0	0	1.3 % (2/150)	98.7 % (148/150)	0	0
Very high	150	803.3	0	0	0	0	0	90.7 % (136/150)	9.3 % (14/150)

b. Variability of Instruments

Instrument-to-Instrument variability was evaluated using three Kenota 1 instruments with one cartridge lot using four fresh venous whole blood samples collected in lithium-heparin anticoagulant-coated blood collection tubes. The study included three trained operators (one operator for each instrument). The total IgE concentration was measured in five replicates for each instrument/operator two times per day for five days, resulting in a total of 150 replicates per sample. The results are summarized in the tables below.

Sample	N	Mean (kU/L)	Repeatability		Between-Run		Between-Day		Between-Instrument/ Operator		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low	150	54.3	7.1	13.1	0.0	0.0	1.8	3.3	0.0	0.0	7.4	13.6
Medium	150	139.4	18.4	13.2	0.0	0.0	6.3	4.5	0.0	0.0	19.5	14.0
High	150	342.4	50.4	14.7	0.0	0.0	14.3	4.2	0.0	0.0	52.4	15.3
Very high	150	802.4	52.4	6.5	9.1	1.1	0.0	0.0	13.0	1.6	54.7	6.8

In addition, the table below provides semi-quantitative analysis using one cartridge lot over three instrument/operator pairs.

Sample	N	Mean (kU/L)	Kenota 1 Total IgE Result Category (kU/L) (%, n/N)						
			< 5	5–34	35–100	101–200	201–540	541–900	> 900
				Very Low	Low	Medium	High	Very High	
Low	150	48.4	0	0.7 % (1/150)	99.3 % (149/150)	0	0	0	0
Medium	150	131.0	0	0	0	100.0 % (150/150)	0	0	0
High	150	312.1	0	0	0	0	99.3 % (149/150)	0.7 % (1/150)	0
Very high	150	803.3	0	0	0	0	0	98.7 % (148/150)	1.3 % (2/150)

c. Repeatability of Fingerstick Whole Blood Samples

An estimate of repeatability of the Kenota 1 Total IgE test was determined using 355 fresh fingerstick whole blood samples covering the analytical measuring interval (AMI) that were collected in the Minivette POCT lithium-heparin tubes. The study was conducted in three CLIA-waived sites in the U.S. and the testing was performed by a total of 11 untrained operators (three untrained operators at Site 1, three untrained operators at Site 2, and five untrained operators at Site 3). Two different operators each collected a separate fingerstick whole blood specimen from the same patient and tested the sample on two or three Kenota 1 instruments at each site with a single lot of Kenota 1 Total IgE cartridge. The variability of two fingerstick numerical results was calculated for each patient in five semi-quantitative categories. The SD for each semi-quantitative category was calculated as the SD^2 averaged over patients from the category. The results of the repeatability evaluation are presented in the table below.

Result Category	Range (kU/L)	N of Samples	Mean (kU/L)	SD (kU/L)	%CV
Very Low	5 – 34	117	17.9	1.9	10.6
Low	35 – 100	86	63.1	5.5	8.7
Medium	101 – 200	57	142.7	14.0	9.8
High	201 – 540	67	335.7	28.3	8.4
Very High	541 – 900	28	702.6	50.5	7.2
	Entire Range (5–900)	**355**	**162.9**	**13.5**	**8.3**

d. Multi-site Reproducibility

Multi-site reproducibility of the Kenota 1 Total IgE was evaluated at three CLIA-waived sites using a single lot of Kenota 1 Total IgE external controls. The low and high controls were tested by three untrained operators per site in two external control (EC) sessions per day over seven different days using a single lot of Kenota 1 Total IgE cartridge, resulting in a total of 126 data points per control. The result for different components of numeric values is summarized below.

Control	N	Mean (kU/L)	Between-Run		Between-Day		Between-Operator		Between-Site		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low	126	34.0	3.9	11.4	1.0	2.8	1.2	3.4	0.0	0.0	4.1	12.2
High	126	259.5	26.2	10.1	11.2	4.3	9.7	3.8	0.0	0.0	30.1	11.6

2. Linearity:

a. Linearity

Linearity was evaluated according to CLSI document EP06-Ed2 by preparing and testing 11 dilution levels that cover the analytical measuring interval (AMI) of the Kenota 1 Total IgE. The series of dilution samples were prepared by pooling the high and low

human lithium-heparin venous whole blood samples. Each sample dilution was measured in one run with 15 replicates. The Kenota 1 Total IgE was found to be linear at 11 levels spanning the semi-quantitative categories as shown in the table below.

			Observed Kenota 1 Total IgE Result Category (kU/L)						
Sample	**Expected IgE (kU/L)**	**Expected Category (kU/L)**	**< 5**	**5–34**	**35–100**	**101–200**	**201–540**	**541–900**	**>900**
1	981	>900						6.7% (1/15)	93.3% (14/15)
2	787	541-900						100% (15/15)	
3	590	541-900					13.3% (2/15)	86.7% (13/15)	
4	393	201-540					100% (15/15)		
5	197	101-200					100% (15/15)		
6	99	35-100			6.7% (1/15)	93.3% (14/15)			
7	50	35-100			100% (15/15)				
8	26	5-34		100% (15/15)					
9	13	5-34		100% (15/15)					
10	7	5-34		100% (15/15)					
11	4	< 34	53.3% (8/15)	46.7% (7/15)					

b. Hook Effect

The dynamic range of the Kenota 1 Total IgE for hook effect was evaluated using a series of venous whole blood samples (1102–6300 kU/L) above the upper limit of the test's AMI prepared from a high contrived sample that was tested in five replicates per sample. Samples with concentration of 1102 kU/L have: 20% (1 out 5) "Very High" results (541–900 kU/L) and 80% (4 out 5) ">900 kU/L" results. Samples with concentrations of 1323, 2319, 3314, 4309, 5305, and 6300 kU/L had 100% (5 out 5) ">900 kU/L" results. No hook effect was observed up to 6300 kU/L.

3. Interference and Cross-Reactivity:

a. Interference

Interference was evaluated according to CLSI document EP07-Ed3 and EP37-Ed1 by testing human lithium-heparin venous whole blood samples at two IgE levels (low and

high category) for potential interfering substances. Each test sample was spiked with a known amount of potentially interfering substances and analyzed at a minimum of six replicates. The interference was calculated by comparing test samples spiked with the potential interferents to control samples spiked with the same volume of diluent. When interference was detected at the initial single dose testing, a dose-response assessment was conducted to identify the amount of the interfering substance within ±10% difference between the test and control sample. No significant interference was observed (within ±10% difference between the control and spiked sample) for the Kenota 1 Total IgE up to the concentrations of the potential interfering and cross-reacting substances tested as shown in the tables below.

Endogenous Interferents	
Substance	**Concentration with No Interference**
Bilirubin (conjugated)	475 µmol/L
Triglycerides	1500 mg/dL
Rheumatoid Factor*	450 IU/mL
Albumin	6 g/dL
Creatinine	15 mg/dL
Oxalic Acid	90 µmol/L
HAMA	30 ng/mL
Hemoglobin	1000 mg/dL

* The labeling includes the following limitation statement: Rheumatoid Factor showed a significant interference (>10% bias) at the lowest amount of 112.5 IU/mL when the low category sample was tested.

Exogenous Interferents		
Substance	**Highest Concentration under Therapeutic Treatment**	**Concentration with No Interference**
Acetaminophen	344 µmol/L	1030 µmol/L
Acetylsalicylic Acid	55.5 µmol/L	167 µmol/L
Ascorbic Acid	99.4 µmol/L	298 µmol/L
Caffeine	185 µmol/L	556 µmol/L
Cetirizine	3.73 µmol/L	11.2 µmol/L
Diphenhydramine	1.01 µmol/L	3.03 µmol/L
Ethanol	2 g/L	6 g/L
Fexofenadine	0.764 µmol/L	2.29 µmol/L
Gentisic Acid	32.4 µmol/L	97.3 µmol/L
Heparin	110 units/dL	330 units/dL
Omalizumab*	54 µg/mL	N/A

* The labeling includes the following limitation statement: Omalizumab (XOLAIR) showed a significant interference (> 10% bias) for low and high category IgE samples at all concentrations tested between 25 µg/mL to 100 µg/mL.

b. Cross-reactivity

The cross-reactivity of the Kenota 1 Total IgE with other immunoglobulin isotypes was evaluated based on the same protocol as described in the interference study above. No significant interference (≤ ±10% of difference) was found at the final test concentrations listed in the table below.

Substance	Concentration with No Interference
IgA	800 mg/dL
IgD	320 IU/mL
IgG	3200 mg/dL
IgM	460 mg/dL

4. Assay Reportable Range:

   The reportable range is the same as the analytical measuring interval (AMI) for the Kenota 1 Total IgE of 5–900 kU/L.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   a. Traceability

   The Total Immunoglobulin E (IgE) working calibrators are traceable to the primary reference material WHO 3rd International Standard Human IgE (11/234).

   b. Stability

   A real-time stability study for the Kenota 1 Total IgE was performed in accordance with the CLSI guideline EP25-Ed2.

   Kenota 1 Total IgE (cartridge) stability
   A real-time stability study was performed by testing three human plasma samples (low, medium, and high) using three lots of Kenota 1 Total IgE cartridges paired with Developing Solution on four Kenota 1 instruments (1 to 3 instruments per storage time point) to evaluate performance of the Kenota 1 Total IgE at multiple time points. As a worst-case scenario, each reagent lot was pre-stressed to environmental test conditions that simulated potential winter (-20°C) and summer (40°C) transport profiles for 24 hours and then stored at 21°C throughout the duration of the stability period. Results support the claimed reagent shelf-life stability for the cartridge up to 5 months at 2–8°C.

   Kenota 1 Total IgE external controls stability
   A real-time stability study was performed by testing three lots of the Kenota 1 Total IgE external low and high controls using one lot of the Kenota 1 Total IgE cartridge on one Kenota 1 instrument at multiple time points. Each lot of the Kenota 1 Total IgE external controls was stored at -20°C (recommended storage condition) or under pre-stressed environmental test conditions at 18–25°C for 24 hours and then stored at -20°C throughout the duration of the stability period. Results support the claimed shelf-life stability of the Kenota 1 Total IgE external controls up to 5 months at -20°C.

   Kenota 1 sample collection kit (SCK) and Kenota 1 Developing Solution (DS) stability
   A real-time stability study was performed by testing two human venous whole blood samples (low and high) using four lots of SCK and four lots of DS with one lot of the Kenota 1 Total IgE cartridge on one Kenota 1 instrument at multiple time points. Two SCK-DS lot pairs were stored at 31°C (recommended storage condition at 15–30°C) or

under pre-stressed environmental test conditions that simulated potential winter (-20°C) and summer (40°C) transport profiles for 24 hours and then stored at 31°C throughout the duration of the stability period. Results support the claimed SCK and DS shelf-life stability up to 5 weeks at 15–30°C.

6. Detection Limit:

The Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) studies were conducted in accordance with the CLSI guideline EP17-A2.

a. Limit of Blank (LoB)

The LoB was determined by testing three venous whole blood samples with low total IgE concentrations <3 kU/L and one blank sample using whole blood matrix with no IgE. Each blank /very low sample was tested in 10 replicates on two Kenota 1 instruments for three days (one run per day), using two lots of Kenota 1 Total IgE cartridges to obtain a total of 120 replicates per reagent lot. The LoB was estimated as the 95th percentile of the measurements for each of the lots tested and determined to be the higher estimated LoB from the two lots of Kenota 1 Total IgE cartridges. The LoB of Kenota 1 Total IgE was determined as 1.8 kU/L.

b. Limit of Detection (LoD) / Limit of Quantitation (LoQ)

The LoD and LoQ were determined using four individual low venous whole blood samples. Each LoD sample was tested in 10 replicates, for each of the two lots of Kenota 1 Total IgE cartridges, one run per day for three days to obtain a total of 30 replicates per sample in each reagent lot. The LoD was calculated as the LoB + 1.645/ (1 - [1/4(B-K)]) x SD of the replicates for the low-level samples and determined to be the higher estimated LoD from the two lots of Kenota 1 Total IgE cartridges. The LoD of Kenota 1 Total IgE was determined as 5.0 kU/L. The LoQ was calculated as a concentration with allowable total error of |Bias|+2*SD≤5 kU/L and determined to be the higher estimated LoQ from the two lots of Kenota 1 Total IgE cartridges. The LoQ of Kenota 1 Total IgE was determined as the same as LoD of 5.0 kU/L.

7. Assay Cut-Off:

Not applicable

8. Accuracy (Blood Collector / Instrument):

The performance of the blood collector was evaluated by recovery of test samples run on the Kenota 1 instrument. Fresh venous whole blood was collected using two lots of Minivette POCT Lithium-heparin, 100 µL (Sarstedt). Five blood collectors in each lot were used to collect venous whole blood and prepare two test samples (low at ~ 50 kU/L and high at ~ 450 kU/L) for measuring recovery of IgE. The Standard IgE (3rd International Standard for serum IgE, 11/234) was spiked into the test samples and the recovery was analyzed by the 'measured increase of IgE' over 'expected increase of IgE'. The recovery bias was within ± 10% across two blood collector lots for the samples run on six Kenota 1 instruments.

9. Carry-Over:

   Control and test carryover conditions were evaluated across four Kenota 1 instruments that tested a venous whole blood sample in the 'very low' category (11.4 kU/L) immediately after testing a sample in ">900 kU/L" category (1875 kU/L measured by the predicate). The IgE level was measured in five consecutive cycles of testing 'above measuring range sample – very low sample' for each instrument. No carry-over effect across four Kenota 1 instruments was observed.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Refer to CW230008

2. Matrix Comparison:

   Not applicable; lithium-heparin capillary whole blood is the only sample type for Kenota 1 Total IgE.

C Clinical Studies:

1. Clinical Sensitivity and Clinical Specificity:

   Not applicable

2. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   See Comparison Studies above.

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

The reference range for the Kenota 1 Total IgE was established in accordance with CLSI guideline EP28-A3c by using 117 fingerstick samples collected from 95 adults and 22 pediatric (Refer to FDA Guidance document, Providing Information about Pediatric Uses of Medical Devices (2014)) volunteer donors. All test samples were collected from individuals with no known allergies or eczema and listing no allergy medications on Donor Information Forms, with two replicates per sample. The reference interval was determined by calculating 2.5^{th} and 97.5^{th} percentiles per CLSI EP28-A3c. The results are summarized in the table below.

Age (Years)	Sample (N)	Median (kU/L)	2.5^{th} – 97.5^{th} Percentile of IgE (kU/L)
8 – <22	22	99.8	<5 to 509
22 – 78	95	26.8	<5 to 695

The labeling includes the following statement:

"IgE reference intervals are significantly influenced by age, sex, geographic location, microflora of the gastrointestinal tract, diet of the population, as well as environmental factors such as climate change."

F Other Supportive Instrument Performance Characteristics Data:

The Kenota 1 Total IgE is intended to be used at Point-of-Care (POC) sites, including allergist / immunologist offices with a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver. Operational limits of the Kenota 1 Total IgE were tested in the following series of studies:

1. Temperature and Relative Humidity

   A study was performed to evaluate whether performing tests using a Kenota 1 instrument and Kenota 1 Total IgE cartridges at a wide range of temperature and relative humidity (RH) conditions could lead to erroneous results. If the room temperature and/or humidity conditions exceed the instrument's limit (17–28°C, 10–90% RH) the instrument's failure alert check is triggered. The instruments and cartridges were exposed to seven test conditions (see Test condition 2 to 8 below) and the test was performed using two fresh venous whole blood samples (~ 45 kU/L and ~450 kU/L) in 10 replicates:

   1) Control condition: 22°C, RH 37%
   2) Test condition: 17°C, RH 6%
   3) Test condition: 17°C, RH 88%
   4) Test condition: 28°C, RH 11%
   5) Test condition: 27°C, RH 86%
   6) Test condition: 16°C, RH 32%
   7) Test condition: 29°C, RH 22%
   8) Test condition: 22°C, RH 96%

   The test results were within ± 5% bias in Test Condition 2, 3, and 4 compared to Control condition 1 above. The run was not initiated when the instrument detected the room temperature and/or humidity conditions exceeding the instrument's limit (17–28°C, 10–90% RH) in Test condition 6, 7, and 8 above and the tablet screen displayed an error message (e.g., 'Room Temperature Too High'). This study demonstrates that the test reports valid results only when the testing room temperature and/or relative humidity conditions are within the instrument's operating specification (17–28°C, 10–90% RH) based on the instrument's failure alert check.

2. Instrument on vibrating surface

   A study was performed to evaluate whether performing tests using the instrument in environments subject to vibrations leads to erroneous results. A fresh venous whole blood sample (~ 200 kU/L) was tested in 24 replicates each on a surface with no/minimal environmental vibrations and a surface with extreme environmental vibration. An unbalanced

centrifuge was run at 3000 RPM. A vibration meter was used to detect the vibration for one minute at specific locations that were measured at 0.33g on the top of the centrifuge, 0.09g on the table next to the centrifuge, 0.07g on the side of the instrument, and 0.16g on the top of the instrument. This study demonstrates the test is unaffected (within ±5% bias) by running a test on vibrating surface.

3. Instrument on tilted surface

A study was performed to evaluate whether performing tests using the instrument in environments subject to tilted surface leads to erroneous results. If the tilted surface beyond its specification limit is detected, the instrument's failure alert check is triggered. A fresh venous whole blood sample (~ 175 kU/L) was tested in a control condition (no tilt / 0 degree, 24 replicates), slight tilt (2 degrees, 24 replicates), moderate tilt (4 degrees, 3 replicates), and high tilt (8 degrees, 3 replicates). The test results were within ±5% bias on front/back and left/right tilt at ±2 degrees. The run was not initiated when the instrument detected a front/back and left/right tilt at ±4 degrees and ±8 degrees, showing an error message "Tile Error" on the tablet screen. This study demonstrates that the test reports valid results only when the instrument is placed up to 2-degree tilted angle.

4. Sub-optimal lighting conditions

A study was performed to evaluate test performance when operators perform testing under varying lighting conditions. A fresh venous whole blood sample was (~ 200 kU/L) tested in 48 replicates in each of the following conditions:

1) Control condition: office lighting (≅ 500 lux)
2) Test condition: direct sunlight (≅ 10000 lux)
3) Test condition: dark (≅ 5 lux)

The test results were within ±5% bias in Test condition 2 and 3 compared to Test condition 1 above. This study demonstrates that the test operators were able to perform the tests in various lighting conditions.

5. Mechanical impact on instrument

A study was performed to evaluate whether mechanical impacts (100g object dropped five times from 30 cm) to the instrument could lead to biased results. A fresh venous whole blood sample (~ 220 kU/L) was tested in 24 replicates in each of the following conditions:

1) Control condition: no mechanical impact
2) Test condition: mechanical impact during run initialization failure alert checks
3) Test condition: mechanical impact during sample dispensing
4) Test condition: mechanical impact during cartridge imaging

The test results were within ±5% bias in Test condition 2, 3 and 4 compared to Control condition 1 above. This study demonstrates that the test is unaffected by mechanical impacts on the instrument during different stages of testing.

6. Samples with air bubbles

A study was performed to determine the ability of the instrument's failure alert check to detect the presence of air bubbles in the sample after the instrument mixes the sample in the sample collection kit (SCK). Air bubbles introduced into the SKC syringe are typically resolved by the sample mixing performed by the instrument and unresolved bubbles are assessed by a failure alert check, preventing SCK with large bubbles from beginning a run. If air bubbles exceeding the size limit are detected by the instrument, the failure alert check is triggered. A fresh venous whole blood sample (~ 194 kU/L) was tested in 24 replicates with (Test condition) and without (Control condition) induced air bubbles. For the test condition, air bubbles were intentionally introduced until two sample syringes passed the run initialization failure alert checks (approximately 1–4 µL air bubble size). The test results were within ±5% bias in Test condition compared to Control condition. This study demonstrates that accurate results can be obtained if operators introduce air bubbles in the test sample up to approximately 4 µL size.

7. Different cartridge positions within the sleeve

A study was performed to determine if the test results are affected by the location within the stack of cartridges in the sleeve. Each sleeve holds up to 15 cartridges. A fresh venous whole blood sample (~ 200 kU/L) was used to evaluate using cartridges in three different location categories (Low: position 1–5, Middle: position 6–10, High: position 11–15). The sample was tested in 12 runs with 5 replicates per run that generated a total of 60 replicates per location category (e.g., 60 results from Low category). The average of test results was < ±5% bias in comparison by the location category (Low, Middle, and High). This study demonstrates that the test results are unaffected by different cartridge positions within the sleeve.

VIII Proposed Labeling:

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

IX Conclusion:

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