510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K182479

B. Purpose for Submission:

New assay and new instrument

C. Measurand:

Allergen specific IgE

D. Type of Test:

Chemiluminescent, Quantitative

E. Applicant:

Hycor Biomedical, LLC

F. Proprietary and Established Names:

NOVEOS™ Specific IgE (sIgE) Assay, Capture Reagent House Dust Mite D001, *Dermatophagoides pteronyssinus*

NOVEOS™ Immunoassay Analyzer

G. Regulatory Information:

1. Regulation section:

   21 CFR §866.5750 – Radioallergosorbent (RAST) immunological test system
   21 CFR §862.2160 – Discrete photometric chemistry analyzer for clinical use

2. Classification:

   Class II – Assay
   Class I – Instrument

3. Product code:

   DHB – System, test, radioallergosorbent (RAST), immunological
   JJE – Analyzer, chemistry (photometric, discrete), for clinical use

4. Panel:

   Immunology (82)
   Chemistry (75)

H. Intended Use:

1. Intended uses:

   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.

   The NOVEOS™ Immunoassay Analyzer is an automated chemiluminescent immunoassay analyzer for measurement of analyte concentration in human specimens. It is intended for in vitro diagnostic use in the clinical laboratory.

2. Indications for use:

   Same as intended use

3. Special conditions for use statement:

   For prescription use only

4. Special instrument requirement:

   For use on the NOVEOS™ Immunoassay Analyzer

I. Device Description:

The NOVEOS™ sIgE Assay consists of the following reagents:

- IgE Common Kit:
  - Diluent A (human serum albumin in buffer with preservative)
  - Conjugate IgE (horse radish peroxidase labeled mouse monoclonal anti-IgE antibody with preservative)
  - Substrate A
  - Substrate B
  - Fluo Beads (streptavidin coated magnetic particles with preservative)
- Capture Reagent Pack
  - House Dust Mite D001, *Dermatophagoides pteronyssinus*
- IgE Calibrator Set (six levels: 0.07, 0.35, 0.70, 3.5, 17.5, 100 kU/L)
- IgE Calibrator Antibody Pack (mouse monoclonal anti-human IgE with preservative)

- IgE Positive Control Pack (known to be >0.35 kU/L)
- IgE Negative Control Packs (known to be <0.35 kU/L)
- Others:
    - Probe Wash Pack (phosphate buffered citric acid solution with preservative)
    - Wash Buffer Concentrate Pack (10X phosphate buffer saline solution with preservative)
    - Cuvette Wash Pack (citric acid solution with preservative)
    - Sample Wash Pack (citric acid solution with preservative)

The NOVEOS™ Immunoassay Analyzer is a high-throughput, highly automated immunoassay platform that employs magnetic microbeads as the solid phase. The immunoassay reaction takes place in individual reaction chambers in the reaction rotor, with other rotors containing patient samples and reagents. Liquids are moved by robotic pipettors. The reaction is quantitated by a combination of chemiluminescence and fluorescence measurements compared to a calibration curve, all performed by the analyzer with the NOVEOS software.

J. Substantial Equivalence Information:

1. Predicate device name and 510(k) number:

   ImmunoCAP Specific IgE Assay and ImmunoCAP Specific IgE Conjugate 100 and Conjugate 400 (K051218)

2. Comparison with predicate:

Similarities		
Item	**Device** NOVEOS™ sIgE Assay	**Predicate** ImmunoCAP Specific IgE Assay (K051218)
Intended Use	The NOVEOS™ Specific IgE is an *in vitro* quantitative assay for the measurement of allergen specific IgE in human serum. NOVEOS Specific IgE 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.
Assay Type	Quantitative	Same

Similarities		
Item	**Device** NOVEOS™ sIgE Assay	**Predicate** ImmunoCAP Specific IgE Assay (K051218)
Allergen	Whole extract of allergen material: House Dust Mite, *Dermatophagoides pteronyssinus*	Same
Traceability	World Health Organization (WHO) reference reagent serum Immunoglobulin E (IgE) 11/234	Same
Number of Calibrators	Six	Same
Reaction Temperature	37 ºC	Same

Differences		
Item	**Device** NOVEOS™ sIgE Assay	**Predicate** ImmunoCAP Specific IgE Assay (K051218)
Specimen Type	Serum	Serum and plasma (EDTA, Na-Heparin)
Solid Phase	Magnetic microbeads	Cellulose derivative
Instrument(s)	NOVEOS™ Immunoassay Analyzer	Phadia 100, Phadia 250/1000/ 2500/5000
Assay Principle	Chemiluminescent assay	Fluoroenzymeimmunoassay
Detection Antibody	HRP conjugated mouse anti-human IgE monoclonal antibody	β-Galactosidase conjugated mouse anti-human IgE monoclonal antibody
Sample Volume	4 µL	40 µL
Detection Limit	LoB: 0.03 kU/L LoD: 0.07 kU/L LoQ: 0.17 kU/L	LoB: 0.001 kU/L LoD: 0.02 kU/L LoQ: 0.10 kU/L
Assay Range	0.17 – 100 kU/L	0.10 – 100 kU/L
Assay Duration	1 hour and 45 minutes	Phadia 100: 2 hours and 30 minutes Phadia 250/1000/2500/5000: 1 hour and 45 minutes from entering the first sample

K. Standard/Guidance Document Referenced (if applicable):

- CLSI I/LA20-A3, Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies and Defined Allergen

Specificities, Approved Guideline–Third Edition
- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline–Third Edition.
- CLSI EP6-A, Evaluation of Linearity of Quantitative Measurement, Approved Guideline
- CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition
- CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents, Approved Guideline

L. Test Principle:

The NOVEOS™ sIgE Assay is an immunometric, chemiluminescent assay for the quantitative determination of IgE of known specificity in human serum samples. Magnetic beads coated with streptavidin and fluorescent dye are incubated with a biotinylated allergen that binds to the streptavidin molecule on the surface of the beads. The beads are collected by use of a magnetic field to remove the liquid, and then undergo a wash step to remove unbound biotinylated allergen prior to incubation with the sample. If present in the sample, sIgE binds to the captured biotinylated allergen. After incubation, the beads are washed and subsequently incubated with an HRP-labeled anti-IgE monoclonal antibody (Conjugate IgE) to form an antibody-conjugate complex that is bound to the captured biotinylated allergen. After washing away the non-bound conjugate, a chemiluminescent substrate is added to the assay mixture resulting in light generation in proportion to the amount of antibody-conjugate that has been bound to the beads. The fluorescence is used to correct for any bead loss during the assay, and the (corrected) chemiluminescence is compared to a calibration curve to provide quantification of bound sIgE. The higher the value of chemilumiscent signal detected by the instrument, the higher the amount of sIgE detected in the sample tested.

M. Performance Characteristics:

1. Analytical performance: All results presented below met the manufacturer's pre-determined acceptance criteria.

   a. Precision/Reproducibility:

      i) Within-laboratory imprecision:

      Imprecision of the NOVEOS™ sIgE Assay, D001 was evaluated by testing a panel of eight (two negative and six positive) serum samples with concentrations that cover the assay range. Samples were tested in two replicates per run, two runs per day for 20 days using one reagent lot on two NOVEOS™ Immunoassay Analyzers for a total of 80 replicates per 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	Mean (kU/L)	Within-Run		Between-Run		Between-Day		Total	
		SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
LOQ1	0.17	0.01	8.4	0.03	16.3	0.01	7.1	0.03	19.7
PP02	0.32	0.02	6.6	0.02	5.1	0.02	5.1	0.03	9.8
PP03	1.70	0.07	4.0	0.09	5.1	0.04	2.6	0.12	7.0
PP04	9.20	0.48	5.2	0.11	1.2	0.34	3.7	0.60	6.5
PP05	0.50	0.02	3.4	0.03	5.2	0.02	4.0	0.04	7.3
PP7	0.47	0.02	5.3	0.03	6.1	0.02	3.3	0.04	8.7
PP08	15.05	0.91	6.0	0.00	0.0	1.06	7.0	1.39	9.3
PP10E	79.98	3.51	4.4	3.68	4.6	3.50	4.4	6.17	7.7

ii) Lot-to-lot imprecision:

Three different lots of the NOVEOS™ sIgE Assay, D001 were evaluated using a panel of five (one negative and four positive) serum samples in five replicates per run, one run per day for five days (for a total of 75 replicates per sample). The results are summarized in the following table:

Sample	Mean (kU/L)	Within-Run		Between-Day		Between-Lot		Total	
		SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
LOQ 3	0.21	0.01	4.7	0.01	4.6	0.01	3.7	0.02	7.6
PP2	0.37	0.02	5.2	0.02	5.1	0.04	9.6	0.05	12.1
PP4	11.02	0.49	4.5	0.34	3.1	1.30	11.8	1.43	13.0
PP40	27.41	1.43	5.2	0.97	3.5	3.26	11.9	3.69	13.5
PP12	80.02	3.98	5.0	3.85	4.8	6.69	8.4	8.69	10.9

iii) Site-to-site reproducibility:

A panel of six patient (one negative and five positive) serum samples and two controls (LYP and NOV) was assayed at three sites using the same lot of reagent. Each sample was tested in five replicates per run, one run per day for five days on one NOVEOS™ Immunoassay Analyzer at each site (for a total of 75 replicates per sample). The results are summarized in the following table:

Sample	Mean (kU/L)	Within-Run		Between-Day		Between-Site		Total	
		SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
LOQ3	0.19	0.01	5.3	0.00	0.0	0.00	0.0	0.01	5.3
PP05*	0.50	0.08	15.9	0.00	0.0	0.05	10.0	0.10	19.9
PP03^	1.83	0.14	7.6	0.04	2.2	0.09	4.9	0.17	9.3
PP04	9.79	0.44	4.5	0.16	1.6	0.50	5.1	0.69	7.0
PP14	30.29	1.49	4.9	0.55	1.8	1.02	3.4	1.88	6.2
PP13	73.78	3.86	5.2	0.00	0.0	2.89	3.9	4.82	6.5
LYP	10.51	0.58	5.5	0.17	1.6	0.65	6.2	0.89	8.5
NOV	29.85	1.80	6.9	0.77	2.6	0.91	3.0	2.16	7.2
* includes an outliner with a value of 1.20 kU/L ^ includes an outliner with a value of 2.67 kU/L									

b. Linearity/assay reportable range:

Linearity of the assay was evaluated following CLSI guideline EP6-A by preparing four dilution series. Four positive serum samples were each diluted in negative serum pool generating at least five 2-fold consecutive dilutions. Each diluted sample was tested in replicates of four in one assay run using three lots of reagents. Results of the replicates for all four samples were analyzed for linearity. Regression statistics comparing the observed results (y) to expected results (x) of all samples in the four-dilution series are presented in the table below for one representative lot.

Dilution Range (kU/L)	Regression Equation	Slope (95% CI)	Intercept (95% CI)	R^2
0.03–133.27	y=1.01x + 0.18	0.99–1.04	−0.82–1.19	1.00

The data summarized in the table above support linearity throughout the claimed measuring range from 0.17 kU/L to 100 kU/L.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

i. <u>Traceability</u>:

The IgE calibrators are traceable to the World Health Organization (WHO) third International Standard 11/234 of Human Serum Immunoglobulin E.

ii. <u>Kit Stability</u>:

Shelf life stability: Both an ongoing real-time stability study and an accelerated stability study were performed in accordance with CLSI EP25-A using three lots of NOVEOS™ sIgE Assay, D001. The accelerated stability data support the manufacturer's claim of 24 to 48 month unopened shelf-life stability for the individual assay components listed in the table below. The real-time stability

study is on-going and available data supports six-month unopened shelf-life stability when stored at 2–8 ºC per the manufacturer's instruction for use:

		Shelf-life Stability* (2–8 ºC)
Specific IgE Capture Reagent D001		24 months
IgE Common Kit	Diluent A	48 months
	Conjugate IgE	18 months
	Substrate A and B	24 months
	Fluo Beads	12 months
IgE Calibrator Set		24 months
Calibrator Antibody IgE		24 months
Controls	IgE Positive Control Pack	24 months
	IgE Negative Control Pack	48 months
Others	Wash Buffer Concentrate	48 months
	Sample Wash Pack	48 months
	Cuvette Wash Pack	24 months
	Probe Wash Pack	24 months
*Results based on accelerated stability data		

On-board stability: A real-time stability study using three lots of NOVEOS™ sIgE Assay, D001 support the on-board stability claim of 48 hours to 28 days for the individual assay components as summarized in the table below.

		On-board Stability* (2–8ºC)
Specific IgE Capture Reagent D001		28 days
IgE Common Kit	Diluent A	14 days
	Conjugate IgE	14 days
	Substrate A and B	14 days
	Fluo Beads	14 days
IgE Calibrator Set		48 hours
Controls	IgE Positive Control Pack	48 hours
	IgE Negative Control Pack	48 hours
Others	1x Wash Buffer	28 days
	Sample Wash Pack	5 days
	Cuvette Wash Pack	28 days
	Probe Wash Pack	Not applicable
*Results based on real-time stability data		

d. Detection limit:

The limit of blank (LoB), limit of detection (LoD), and limit of Quantitation (LoQ) of the NOVEOS™ sIgE Assay, D001 on the NOVEOS™ Immunoassay Analyzer were

determined according to CLSI guideline EP17-A2.

LoB was determined by testing three IgE-free human serum samples in ten replicates per run, one run per day, for three days on two analyzers using two lots of NOVEOS™ sIgE Assay, D001. The LoB was estimated as the 95th percentile of 90 measurements for each of the lots tested.

LoD was determined using five serum samples with low IgE concentrations. Each sample was tested in replicates of ten per run, two runs per day, for three days on two analyzers using three lots of NOVEOS™ sIgE Assay, D001. The LoD was determined for each lot based on 900 measurements as the mean concentration of the lowest sample with 95% or more of its replicates recovering above the LoB.

LoQ was determined as functional sensitivity using a set of 15 samples with low IgE concentrations. Each sample was tested in replicates of two per run, one run per day, for 20 days with three reagent lots on two instruments for a total of 80 data points per sample per reagent lot. The LoQ is defined as the mean value of the sample 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.

	LoB	**LoD**	**LoQ**
NOVEOS sIgE Assay, D001	0.03 kU/L	0.08 kU/L	0.17 kU/L

e. *Analytical specificity:*

i. Inhibition study:

Immunological specificity of D001 (*Dermatophagoides pteronyssinus*) allergen was verified through competitive inhibition according to CLSI guideline I/LA20-A3. A positive sample with specific IgE concentration of 43.2 kU/L was used in the study.

The D001 allergen solution (inhibitor) was diluted into the positive serum sample to achieve a starting concentration of 100 µg/mL. The D001 sample solution was serially diluted five times in two folds and each diluted sample was evaluated for dose-dependent inhibition in five replicates with three lots of NOVEOS™ sIgE Assay, D001. The results of the dose-dependent inhibition study showed that 83% inhibition was achieved with D001 at a final inhibitor concentration of 3.1 µg/mL. The related allergen D070 (Storage mite), and the unrelated allergen, E006 (Guinea pig epithelium), E085 (Chicken feathers), F001 (Egg white), G006 (Timothy grass) and W003 (Giant ragweed) were also tested as potential inhibitors at a final concentration of at least ten times the concentration of D001 at which >50% inhibition was achieved. All allergen inhibitors were spiked into the positive serum sample at a 1:1 dilution and evaluated with three lots of

NOVEOS™ sIgE Assay, D001. The results of the single-dose inhibition studies using one related allergen (D007) and five unrelated allergens (E006, E085, F001, G006 and W003) did not show inhibition (<15%) at a test concentration of 31.3 µg/mL for the related allergen and 1.2 mg/mL for the five unrelated allergens. The inhibition studies indicate that the NOVEOS™ sIgE Assay, D001 contains the immunologically relevant allergen.

ii. Interference

a) Endogenous Substance Interference:

The effect of the presence of elevated level of human albumin, hemoglobin, triglyceride, conjugated bilirubin, and rheumatoid factor in serum samples was evaluated by testing four (one negative, three positive including one near 0.35 kU/L) serum samples spiked with varying levels of each interferent and analyzed in ten replicates in one assay run with three lots of NOVEOS™ sIgE Assay, D001. The % recovery for each sample spiked with the interference substance was calculated by comparing its result to that of the corresponding reference sample spiked with an equal volume of the solvent without the interference substance. No interference was noted for samples containing human serum albumin up to 120 mg/mL, hemoglobin up to 200 mg/dL, triglyceride up to 584 mg/dL, conjugated bilirubin up to 30 mg/dL, and rheumatoid factor up to 513 IU/mL.

b) Exogenous Substance Interference:

The same protocol used in the endogenous substance interference study was used to evaluate potentially interfering exogenous substances. No interference was noted for samples containing biotin up to 1200 µg/L, diphenhydramine at 19.6 µmol/L, methylprednisolone at 1000 ng/mL, omalizumab at 0.12 mg/mL and ranitidine at 6.0 µg/L.

iii. Cross-reactivity:

The potential cross-reactivity of non-IgE (IgA, IgD, IgG, and IgM) to the NOVEOS™ sIgE Assay, D001 was evaluated by mixing serum samples spiked with the immunoglobulin stock solutions containing IgA, IgG, and IgM at 77.2 mg/mL and IgD at 81.24 mg/mL with immunoglobulin stripped serum to obtain a series of six two-fold serially diluted samples containing target levels of non-IgE within or above the physiological range. The control samples were prepared by serially diluting equal volumes of distilled water into stripped serum. No cross reactivity was noted up to 20.4 mg/mL for IgA, IgG and IgM, and up to 2.4 mg/mL for IgD.

f. Assay cut-off:

See clinical cut-off

2. Comparison studies:

a. Method comparison with predicate device:

A total of 234 serum samples spanning the measuring range were tested with the NOVEOS™ sIgE Assay, D001 (candidate) and the ImmunoCAP Specific IgE, ImmunoCAP Allergen d1, House dust mite (predicate). Agreement between the candidate and predicate devices was evaluated using a clinical cut-off value of 0.35 kU/L. The results are summarized in the following table:

		ImmunoCAP sIgE, Allergen d1		
		Positive	**Negative**	**Total**
NOVEOS™ sIgE Assay, D001	**Positive**	86	2	88
	Negative	8	138	146
	Total	94	130	234

Positive Agreement: 91.49% (86/94) (95% CI: 84.10–95.62%)
Negative Agreement: 98.57% (138/140) (95% CI: 94.94–99.61%)
Total Agreement: 95.73% (220/234) (95% CI: 92.31–97.66%)

b. Matrix comparison:

Not Applicable

3. Clinical studies:

a. Clinical Sensitivity and Specificity:

To demonstrate the clinical performance of the NOVEOS™ sIgE Assay, D001, test results of the clinical samples from 117 atopic and 119 healthy, non-atopic donors evaluated in the method comparison study were compared to a clinical diagnosis of allergy. The atopic donors with a clinical history of allergy-like symptoms were identified as positive by skin prick testing (SPT) and the non-atopic donors with no reported allergy. The clinical sensitivity and specificity in this study cohort are summarized in the following table:

		Clinical Diagnosis		
		Atopic	**Non-atopic**	**Total**
NOVEOS™ sIgE Assay, D001	**Positive**	90	0	90
	Negative	27	119	146
	Total	117	119	236

Sensitivity = 76.9% (90/117) (95% CI: 68.5%–83.6%)
Specificity = 100.0% (117/119) (95% CI: 96.9%–100.0%)

b. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:

The clinical cut-off of the assay is 0.35 kU/L. The interpretation of results of the assay uses the following classification system:

Class	Concentration (kU/L)	Interpretation
0	<0.35	Negative
I	0.35 to <0.70	Positive with increasing sIgE concentration
II	0.70 to <3.50	
III	0.35 to <17.50	
IV	17.50 to <50.00	
V	50.00 to <100.00	
VI	≥100	

5. Expected values/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, D001 in the normal population was verified by testing samples from 119 apparently healthy subjects in clinical study. All 119 samples were tested below <0.35 kU/L.

N. Instrument Name:

The NOVEOS™ Immunoassay Analyzer

O. System Descriptions:

1. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes ___X_____ or No _____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes _____ or No __X_____

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes ____X____ or No _____

3. Specimen Identification:

   A barcode scanner is part of the instrument system and is used to identify specimens.

4. Specimen Sampling and Handling:

   The instrument system has automated specimen sampling and handling - the Sample Arm transfers samples from tubes in the Sample Rotor to cuvettes in the Reaction Rotor.

5. Calibration:

   All assays use a calibration curve which is generated from six level calibrators. A calibration curve is run with each batch of samples.

6. Quality Control:

   Controls are processed exactly the same as patient samples, but yield known expected results. The manufacturer suggests that quality control specimens be run with each calibration curve to monitor assay performance. The value assigned for the positive control are with a lot-specific 2D barcode that lists what the expected values are for each test that the control supports. Negative Controls for allergy is also coded into the 2D barcode.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Carryover:

Evaluation of instrument carryover was conducted using one lot of reagent of NOVEOS sIgE, D001 on three NOVEOS Immunoassay Analyzers. The carryover assessment is based on 11 cycle counts split over two runs per instrument. Pooled high-level patient samples with sIgE concentration of 73 kU/L were aliquoted into 11 tubes and pooled low-level patient samples with sIgE concerntration of 0.24 kU/L were aliquoted into 55 tubes. During each cycle one high sample is tested followed by five low samples. Low Sample 1 following High Sample is denoted as "possibly affected" which has the highest chance of potential carryover thus leading to signal change > 0.10 kU/L. Low Samples 3-5 is denoted as "very probably unaffected" and therefore should not have elevated kU/L signal. Carryover assessment is done by measuring the change (Δ) of [mean concentration of Low Sample 1] and [mean concentration of Low Samples 3-5]. The results are summarized in the table below:

NOVEOS Immunoassay Analyzers	Mean Conc. of Low Sample 1 (kU/L)	Mean Conc. of Low Sample 3-5 (kU/L)	Δ Carryover (kU/L)
1	0.245	0.243	0.002
2	0.265	0.259	0.006
3	0.216	0.219	-0.003

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

R. Conclusion:

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