

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k100910

B. Purpose for Submission:

Addition of 10 new allergens to a cleared device

C. Measurand:

Ten Allergen Specific IgE: Apricot, Asparagus, Blueberry, Cauliflower, Chili Pepper, Chub Mackerel, Ginger, Lime, Perch, Whey

D. Type of Test:

Quantitative, chemiluminiscent immunoassay

E. Applicant:

Siemens Healthcare Diagnostics, Inc.

F. Proprietary and Established Names:

IMMULITE® 2000 3gAllergy™ Specific IgE Assay kit

G. Regulatory Information:

1. Regulation section:
21 CFR § 866.5750, Radioallergosorbent (RAST) immunological test system
2. Classification:
Class II
3. Product code:
DHB System, Test, Radioallergosorbent (RAST), Immunological
4. Panel:
Immunology (82)

H. Intended Use:

1. Intended use:
For *in vitro* diagnostic use with the IMMULITE 2000 Analyzer – for the quantitative measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders. The test results are to be used in conjunction with clinical findings and other laboratory tests.
2. Indication(s) for use:
Same as Intended use.
3. Special conditions for use statement(s):
For prescription only.
4. Special instrument requirements:
IMMULITE 2000 Analyzer (k970227)

I. Device Description:

Each device contains the following: 3gAllergy™ specific IgE bead pack (3 packs of 200 beads coated with anti-ligand); specific IgE reagent wedge: 30 mL alkaline phosphatase (bovine calf intestine) conjugated to monoclonal murine anti-human IgE antibody in a human/nonhuman serum buffer matrix (equally dispensed in 1 wedge with B & C chambers); specific IgE adjustors: low and high (2 vials, 2 mL each) of human IgE in a nonhuman serum matrix with preservative; specific IgE adjustor antibody: 2 tubes, 2.75 mL each) ready to use ligand-labeled polyclonal goat anti-human IgE antibody with preservative; specific IgE universal kit controls: (2 vials, 2

mL each) human IgE in a nonhuman sample matrix with preservative; specific IgE control antibody: (2 tubes, 2.75 mL each) ready to use ligand-labeled polyclonal goat anti-human IgE antibody with preservative. Kit components supplied separately: 3gAllergy™ specific IgE sample diluent (concentrated ready to use 1 vial, 25 mL); chemiluminiscent substrate; probe wash; probe cleaning kit; disposable reaction tubes; bar coded allergen holder wedges serially coded 1-33; 34 -66; 67-99; allergen tube caps and tube septa.

J. Substantial Equivalence Information:

1. Predicate device name(s) and predicate k number(s):
IMMULITE® 2000 3gAllergy™ Specific IgE, k013134
2. Comparison with predicates:

Similarities		
Item	New Device	Predicate Device
Intended use	For <i>in vitro</i> diagnostic use with the IMMULITE 2000 Analyzer – for the quantitative measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders. The test results are to be used in conjunction with clinical findings and other laboratory tests.	Same
Technology	Chemiluminescence	Same
Assay performance	Specific to allergen-specific IgE	Same
Calibrators	Low and high	Same
Controls	Specific IgE and Antibody and Specific IgE Universal Controls	Same
Sample type	Serum	Same
Result Interpretation	Quantitative values in kU/L; Interpretation of class results for two scoring systems: Standard and Extended standard	Same

Differences		
Item	New Device	Predicate Device
Total number of Allergens	Ten	One hundred and ten
Types of Specific Allergens	10 Specific Food Allergens: Apricot, Asparagus, Blueberry, Cauliflower, Chili Pepper, Chub Mackerel, Ginger, Lime, Perch, Whey	110 Specific Allergens: 8 Animal epithelia, 2 House dusts, 39 Food, 13 Grasses, 5 Insects, 5 Mites, 10 Molds, 1 Latex, 14 Trees, 13 Weeds

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

FDA Guidance – Radioallergosorbent Test (RAST) Methods for Allergen-Specific Immunoglobulin E (IgE) 510(k); Final Guidance
CLSI I/LA 20-A: Evaluation Methods and Analytical Performance Characteristics of Immunological Assays for Human Immunoglobulin E (IgE)
CLSI EP5-A2: Evaluation of Precision Performance of Quantitative Methods; Approved Guideline – Second Edition

L. Test Principle:

The assay is a solid-phase, two-step, chemiluminiscent immunoassay that exploits liquid phase kinetics in a bead format. The allergens are covalently bound to a soluble polymer/co-polymer matrix, which is labeled with a ligand. The assay specific antibody is labeled with alkaline phosphatase. The use of an amino acid co-polymer amplifies the amount of allergen that the matrix can support. The chemiluminiscent detection system is a phosphatase ester of stabilized dioxatane. Cleavage of the phosphate ester by alkaline phosphatase results in the decomposition of dioxatane and the emission of photons, which are quantified by a luminometer.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Reproducibility of the assay was assessed by testing three positive samples and one negative control sample of each (Apricot, Asparagus, Blueberry, Cauliflower, Chili Pepper, Chub Mackerel, Ginger, Lime, Perch, Whey) in duplicate twice a day for 20 different days (n = 80).

The sponsor’s criterion for the negative sample was the average dose level must be <0.10 kU/L; all negative sample mean results were within the acceptance criterion. The sponsor’s acceptance criterion for the positive samples was ≤15% CV for both within-run and total precision. Three allergen lots were tested for each allergen; representative data from one lot is shown below for the positive samples. The intra-assay and inter-assay %CV ranges were from 2.46% to 9.15 % and 2.76% to 11.47%, respectively (see tables below).

Allergen: Apricot

Sample	Mean (kU/L)	Intra-assay		Inter-assay	
		SD (kU/L)	%CV	SD (kU/L)	%CV
Positive #1	15.49	0.538	3.47	0.685	4.42
Positive #2	2.62	0.091	3.49	0.116	4.45
Positive #3	4.30	0.127	2.95	0.164	3.81
Positive #4	0.42	0.028	6.58	0.028	6.69

Allergen: Asparagus

Sample	Mean (kU/L)	Intra-assay		Inter-assay	
		SD (kU/L)	%CV	SD (kU/L)	%CV
Positive #1	4.38	0.151	3.46	0.202	4.61
Positive #2	1.16	0.034	2.94	0.039	3.39
Positive #3	1.58	0.067	4.26	0.095	5.98
Positive #4	0.54	0.041	7.52	0.043	7.85

Allergen: Blueberry

Sample	Mean (kU/L)	Intra-assay		Inter-assay	
		SD (kU/L)	%CV	SD (kU/L)	%CV
Positive #1	3.72	0.157	4.21	0.200	5.37
Positive #2	7.53	0.245	3.25	0.364	4.83
Positive #3	0.91	0.022	2.46	0.025	2.76
Positive #4	0.46	0.018	3.97	0.019	4.20

Allergen: Cauliflower

Sample	Mean (kU/L)	Intra-assay		Inter-assay	
		SD (kU/L)	%CV	SD (kU/L)	%CV
Positive #1	1.25	0.044	3.55	0.058	4.60
Positive #2	4.42	0.163	3.68	0.239	5.39
Positive #3	10.65	0.407	3.82	0.474	4.45
Positive #4	0.49	0.033	6.62	0.044	8.99

Allergen: Chili Pepper

Sample	Mean (kU/L)	Intra-assay		Inter-assay	
		SD (kU/L)	%CV	SD (kU/L)	%CV
Positive #1	0.44	0.019	4.31	0.025	5.65
Positive #2	12.88	0.475	3.69	0.582	4.52
Positive #3	5.29	0.216	4.07	0.259	4.88
Positive #4	1.50	0.103	6.84	0.119	7.89

Allergen: Chub Mackerel

Sample	Mean (kU/L)	Intra-assay		Inter-assay	
		SD (kU/L)	%CV	SD (kU/L)	%CV
Positive #1	0.23	0.012	5.05	0.014	6.23
Positive #2	1.90	0.072	3.78	0.095	5.02
Positive #3	1.67	0.052	3.10	0.065	3.86
Positive #4	12.75	0.536	4.20	0.581	4.56

Allergen: Ginger

Sample	Mean (kU/L)	Intra-assay		Inter-assay	
		SD (kU/L)	%CV	SD (kU/L)	%CV
Positive #1	0.65	0.020	3.02	0.031	4.83
Positive #2	0.51	0.025	4.84	0.027	5.33
Positive #3	9.70	0.329	3.39	0.445	4.58
Positive #4	0.88	0.047	5.35	0.058	6.56

Allergen: Lime

Sample	Mean (kU/L)	Intra-assay		Inter-assay	
		SD (kU/L)	%CV	SD (kU/L)	%CV
Positive #1	1.23	0.032	2.61	0.049	4.03
Positive #2	3.53	0.133	3.77	0.166	4.71
Positive #3	9.10	0.266	2.92	0.346	3.80
Positive #4	0.37	0.034	9.15	0.043	11.47

Allergen: Perch

Sample	Mean (kU/L)	Intra-assay		Inter-assay	
		SD (kU/L)	%CV	SD (kU/L)	%CV
Positive #1	12.82	0.544	4.24	0.685	5.34
Positive #2	14.86	0.596	4.01	0.752	5.06
Positive #3	0.89	0.038	4.28	0.048	5.42
Positive #4	0.47	0.024	4.99	0.028	5.85

Allergen: Whey

Sample	Mean (kU/L)	Intra-assay		Inter-assay	
		SD (kU/L)	%CV	SD (kU/L)	%CV
Positive #1	3.31	0.136	4.11	0.169	5.11
Positive #2	0.70	0.025	3.59	0.026	3.69
Positive #3	1.48	0.071	4.82	0.075	5.09
Positive #4	14.19	0.580	4.09	0.590	4.16

Additional precision studies were performed on 10 allergens for the following concentration levels (see table below):

Class	Specific Allergen	Mean	With-in Run		Total	
			SD	%CV	SD	%CV
Class I 0.35-0.69 kU/L	Apricot	0.42	0.028	6.58	0.028	6.69
Class I 0.35-0.69 kU/L	Asparagus	0.54	0.041	7.52	0.043	7.85
Class I 0.35-0.69 kU/L	Blueberry	0.46	0.018	3.97	0.019	4.20
Class I 0.35-0.69 kU/L	Cauliflower	0.49	0.033	6.62	0.044	8.99
Class II 0.70 – 3.49 kU/L	Chili Pepper	1.50	0.103	6.84	0.119	7.89
Class III 3.50-17.49 kU/L	Chub Mackerel	12.75	0.536	4.20	0.581	4.56
Class II 0.70 – 3.49 kU/L	Ginger	0.88	0.047	5.35	0.058	6.56
Class I 0.35-0.69 kU/L	Lime	0.37	0.034	9.15	0.043	11.47
Class I 0.35-0.69 kU/L	Perch	0.47	0.024	4.99	0.028	5.85
Class III 3.50-17.49 kU/L	Whey	14.19	0.580	4.09	0.590	4.16

Lot to lot imprecision:

The three tested lots were analyzed for lot-to-lot precision using three positive and one negative samples. Within run imprecision between lots ranged from 2.60% to 8.82% and total imprecision from 4.19% to 9.64%. All three lots were within the sponsor's claimed acceptable criterion of $\leq 20\%$ variability.

b. Linearity/assay reportable range:

Linearity studies: For each allergen, two clinical samples were diluted in 2-

fold serial dilutions to 5 levels. The undiluted (neat) and diluted samples were tested with the specific allergen to demonstrate linearity at concentrations within the assay limits. Regression statistics for each allergen comparing the observed results to expected results are presented below:

Allergen	Regression Equation	Slope 95% CI	Intercept 95% CI
F237 - Apricot	Y=0.992x -0.0483	0.960 to 1.024	-0.1487 to 0.0520
F261 - Asparagus	Y=1.001x +0.0411	0.974 to 1.028	-0.0099 to 0.0921
F288 - Blueberry	Y=1.001x +0.0396	0.974 to 1.028	-0.0597 to 0.1388
F291 - Cauliflower	Y=1.002x +0.0688	0.976 to 1.028	-0.0032 to 0.1407
F279 - Chili Pepper	Y=1.010x +0.4801	0.969 to 1.052	-0.0739 to 1.0341
F50 - Chub Mackerel	Y=1.015x +0.2718	0.968 to 1.062	-0.2001 to 0.7436
F270 - Ginger	Y=0.992x -0.0051	0.966 to 1.017	-0.0675 to 0.0573
F306 - Lime	Y=0.999x -0.0175	0.981 to 1.018	-0.0737 to 0.0386
F65 - Perch	Y=0.998x -0.1182	0.959 to 1.037	-0.2515 to 0.0152
F236 - Whey	Y=0.999x -0.0074	0.980 to 1.017	-0.0875 to 0.0728

IMMULITE 2000 3gAllergy Universal Kit Total IgE working range: 0.1 - 100 kU/L

- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
 Traceability: The calibrators and controls are traceable to the WHO 2nd IRP 75/502 reference standard for human IgE.

Stability:

Allergen stability: Accelerated allergen stability testing (15-25°C for 57 days; assay kits stored at recommended temperature 2-8°C). The accelerated study supports a two year shelf-life stability claim.

On-board/ open stability:

Testing was performed for 21 days. On-going data collection is for >90 days. Current study supports the 21 day stability claim.

Testings were performed on two positive samples and one negative sample on days 1, 7, 14, 21, 30, 45, 60, 75, 91 for each individual specific allergen.

Stability studies support the 90 day stability claim.

Adjustment interval (calibration curve) stability: Testing was performed at days 1 and 14 to validate the 2-week adjustment interval. The calibration curve stability study supports the 2 weeks stability claim.

Sample stability: Stress conditions representing the storage claims were set up at 3 and 7 days at 2-8°C and 6 months at -20°C. No significant variation to the reference samples that were run at day 0 was observed. The sample stability study supports the 7 days at 2-8°C and 6 months at -20°C stability claims.

- d. *Detection limit:*

Limit of Blank (LoB): Three runs assaying the blank sample (zero calibrator)

were performed to estimate the LoB. A total of three instruments were used per run. The maximum dose of the LoB was selected as the most conservative LoB: $LoB_{MAX} = 0.026$ kU/L. The claimed LoB is 0.1 kU/L.

Limit of Detection (LoD): Five samples were used to estimate the LoD. Sixty replicates of each sample were assayed per run. A total of 2 runs were completed with testing performed on 2 different instruments. The LoD was calculated for each sample using the formula: $LoD = LoB_{MAX} + (1.65 * SD_{LOD})$. The claimed LoD is 0.1 kU/L

e. *Analytical specificity:*

Inhibition studies: Specificity of each allergen was verified through competitive inhibition testing using a single serum sample or a serum pool. A negative sample was used to measure the background response.

To initiate the inhibition experiment, 70 μ L of undiluted and 3-4 levels of 5-fold serially diluted inhibitor extract were mixed with 250 μ L of sample or pool to achieve final inhibitor concentrations of 218.75, 43.75, 8.75, 1.75, 0.35, 0.08, 0.07, 0.02, 0.01, 0.003 μ g/mL inhibitor. This mixture was incubated at room temperature (15-28°C) for 1 hour allowing the immunological reaction to occur. Each sample mixture containing the inhibitor extract and the appropriate controls was assayed with 1 lot of each allergen. The percent (%) inhibition was calculated according to the following formula:

$$\frac{(\text{Response of pos. control}_{(\text{pos. sample} - \text{neg. sample})} - \text{sample response with inhibitor extract})}{(\text{Response of pos. control}_{(\text{pos. sample} - \text{neg. sample})})} \times 100$$

The inhibition plots demonstrate that the allergens tested are inhibited by the relevant inhibitor extract in a concentration dependent fashion. Also, the target % inhibition of 50% for the highest inhibitor concentration tested was met. These results indicate specificity of Apricot, Asparagus, Blueberry, Cauliflower, Chili Pepper, Chub Mackerel, Ginger, Lime, Perch and Whey allergens.

Additional inhibition studies were conducted to show that the specific allergens are not cross-reacting to the unrelated allergens. Testing was performed using one positive sample with three unrelated allergen extracts at 1 mg/mL. A negative sample was used to measure the background response. Results on the positive sample for the following specific allergens were below 9.9%: Apricot, Asparagus, Blueberry, Cauliflower, Chili Pepper, Chub Mackerel, Ginger, Lime, Perch and Whey.

Cross-reactivity: The manufacturer states there is no detectable crossreactivity with human serum immunoglobulins IgG, IgA, IgM or IgD at normal physiological levels.

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Refer to Clinical studies

b. *Matrix comparison:*

Not applicable. Serum is the only matrix.

3. Clinical studies:

a. Clinical Sensitivity and Specificity

Clinical performance of the IMMULITE® 2000 3gAllergy Specific IgE assay for Apricot, Asparagus, Blueberry, Cauliflower, Chili Pepper, Chub Mackerel, Ginger, Lime, Perch, Whey allergens was demonstrated by testing samples from non-atopic and atopic individuals. Atopic patients were selected from patients who had clinical documentation of allergy to specific allergen(s) or allergen group of interest and/or positive skin prick/ scratch test to specific allergen(s) of interest evaluated as 2+ or greater. Information on the skin test allergen extracts (crude or purified) was not documented. Non-atopic patients were clinically known non-allergic or total IgE <130 ng/mL or 54 IU/mL (2.4 ng = 1 IU). Testing was performed on 150 samples for Apricot, 148 samples for Asparagus, 148 samples for Blueberry, 138 samples for Cauliflower, 136 samples for Chili Pepper, 136 samples for Chub Mackerel, 130 samples for Ginger, 143 samples for Lime, 136 samples for Perch, and 133 samples for Whey.

Sensitivity and specificity of the new device, based on diagnosis of atopic status, are shown in the tables below:

<u>Allergen: Apricot</u>		Clinical Diagnosis		
		Atopic	Non-atopic	Total
IMMULITE 2000	positive	43	3	46
	negative	5	99	104
	Total	48	102	150

Sensitivity: 90% (43/48) (95% CI: 81-98%)

Specificity: 98 % (99/102) (97% CI: 94-100%)

<u>Allergen: Asparagus</u>		Clinical Diagnosis		
		Atopic	Non-atopic	Total
IMMULITE 2000	positive	32	2	34
	negative	16	98	114
	Total	48	100	148

Sensitivity: 67% (32/48) (95% CI: 53-80 %)

Specificity: 98 % (98/100) (95% CI: 95-100 %)

<u>Allergen: Blueberry</u>		Clinical Diagnosis		
		Atopic	Non-atopic	Total
IMMULITE 2000	positive	38	2	40
	negative	10	98	108
	Total	48	100	148

Sensitivity: 79% (38/48) (95% CI: 68-91-%)

Specificity: 98% (98/100) (95% CI: 95-101%)

<u>Allergen: Cauliflower</u>		Clinical Diagnosis		
		Atopic	Non-atopic	Total
IMMULITE 2000	positive	32	5	37
	negative	6	95	101
	Total	38	100	138

Sensitivity: 84% (32/38) (95% CI: 73-96%)

Specificity: 95% (95/100) (95% CI: 91-100%)

<u>Allergen: Chili Pepper</u>		Clinical Diagnosis		
		Atopic	Non-atopic	Total
IMMULITE 2000	positive	28	5	33
	negative	8	95	103
	Total	36	100	136

Sensitivity: 78% (28/36) (95% CI: 64-91%)

Specificity: 95% (95/100) (95% CI: 91-99%)

<u>Allergen: Chub Mackerel</u>		Clinical Diagnosis		
		Atopic	Non-atopic	Total
IMMULITE 2000	positive	15	3	18
	negative	21	97	118
	Total	36	100	136

Sensitivity: 42% (15/36) (95% CI: 26-58%)

Specificity: 97% (97/100) (95% CI: 94/100%)

<u>Allergen: Ginger</u>		Clinical Diagnosis		
		Atopic	Non-atopic	Total
IMMULITE 2000	positive	19	4	23
	negative	11	96	107
	Total	30	100	130

Sensitivity: 63% (11/30) (95% CI: 46-81%)

Specificity: 96% (96/100) (95% CI: 92-100%)

Allergen: Lime		Clinical Diagnosis		
		Atopic	Non-atopic	Total
IMMULITE 2000	positive	38	5	43
	negative	5	95	100
	Total	43	100	143

Sensitivity: 88% (38/43) (95% CI: 79-88%)

Specificity: 95% (95/100) (95% CI: 91-100%)

Allergen: Perch		Clinical Diagnosis		
		Atopic	Non-atopic	Total
IMMULITE 2000	positive	17	2	19
	negative	19	98	117
	Total	36	100	136

Sensitivity: 47% (17/36) (95% CI: 31-64%)

Specificity: 98% (98/100) (95% CI: 95-101%)

Allergen: Whey		Clinical Diagnosis		
		Atopic	Non-atopic	Total
IMMULITE 2000	positive	20	6	26
	negative	13	94	107
	Total	33	100	133

Sensitivity: 61% (20/33) (95% CI: 44-77 %)

Specificity: 94% (94/100) (95% CI: 89-100 %)

Literature support was provided on allergens with low prevalence and % sensitivity as shown below:

Allergen (Specific Allergen/% Clinical Sen.)	Literature(s)	General Fish Allergy Prevalence	Clinical Sensitivity
Chub Mackerel: (F50/42%)	1. O'Neil C, Helbling AA, Lehrer SB. Allergic reactions to fish. Clin Rev Allergy. 1993 Summer; 11(2):183-200. 2. Pereira B, Venter C, Grundy J, Clayton CB, Arshad SH, Dean T. Prevalence of sensitization to food allergens, reported adverse reaction to foods, food avoidance, and food hypersensitivity among teenagers. J Allergy Clin Immunol. 2005 Oct;116(4):884-92	6.9-10.3% fish (in children) ¹ 8-15% fish (young adults) ²	10-60% (in a fish sensitive population) ¹

Allergen (Specific Allergen/% Clinical Sen.)	Literature(s)	General Fish Allergy Prevalence	Clinical Sensitivity
Perch: (F65/47%)	1. O'Neil C, Helbling AA, Lehrer SB. Allergic reactions to fish. Clin Rev Allergy. 1993 Summer; 11(2):183-200. 2. Pereira B, Venter C, Grundy J, Clayton CB, Arshad SH, Dean T. Prevalence of sensitization to food allergens, reported adverse reaction to foods, food avoidance, and food hypersensitivity among teenagers. J Allergy Clin Immunol. 2005 Oct;116(4):884-92	6.9-10.3% fish (in children) ¹ 8-15% fish (young adults) ²	38-56% (in a fish sensitive population) ¹

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

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not detected.

Refer to the Hoffman's 'Standard' and 'Extended Standard' classification system utilizing Class 0 to Class IV cut-offs (see Tables I and II below).

Table-I: The Standard classification system utilizes the following class cutoffs:

Class	kU/L	Reactivity for Individual/ Component Allergen(s)
0*	< 0.10	Absent or ND [†]
	0.10 – 0.34	Very Low
I	0.35 – 0.69	Low
II	0.70 – 3.49	Moderate
III	3.50 – 17.49	High
IV	17.5 – 52.49	Very High
V	52.5 – 99.99	
VI	≥ 100	

* Class 0 in the standard system signifies: not detectable by second-generation assays.

[†] ND: not detectable by IMMULITE 2000 3gAllergy.

Table-II: The Extended standard classification system utilizes the following class cutoffs.

Class	kU/L	Reactivity for Individual/ Component Allergen(s)
0	< 0.10	Absent or ND [†]
0/1	0.10 – 0.24	Very Low
I	0.25 – 0.39	Low
II	0.40 – 1.29	Moderate
III	1.30 – 3.89	High
IV	3.90–14.99	Very High
V	15.00– 24.99	
VI	≥ 25	

[†] ND: not detectable by IMMULITE 2000 3gAllergy

The choice of classification systems can be made by the user within the IMMULITE 2000 operational software.

Reference: Hoffman, DR. Comparison of methods of performing the Radioallergosorbent test: Phadebas, Fadal-Nalebuff and Hoffman protocols. Ann Allergy. 1980 Dec; 45(6)

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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