510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K202541

B Applicant

Phadia AB

C Proprietary and Established Names

EliA RNA Pol III

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NYO	Class II	21 CFR 866.5100 - Antinuclear Antibody Immunological Test System	IM - Immunology

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

IgG autoantibodies specific to RNA polymerase III (RNA Pol III) proteins

C Type of Test:

Automated semi-quantitative solid phase fluoroimmunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

EliA RNA Pol III is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to RNA polymerase III (RNA Pol III) in human serum as an aid in the diagnosis of systemic sclerosis (diffuse form) in conjunction with other laboratory and clinical findings. EliA RNA Pol III uses the EliA IgG method.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

For use on the Phadia 250 instrument and the Phadia 2500 and Phadia 5000 instrument series (E-modules).

IV Device/System Characteristics:

A Device Description:

EliA uses a modular reagent system. The test specific, method specific and general reagents are packaged and purchased separately.

EliA RNA Pol III Assay-Specific Reagents include:

- EliA RNA Pol III Wells: coated with human recombinant RNA polymerase III proteins – two carriers (12 wells each), ready to use.
- EliA ANA 3 Positive Control 250 or 2500/5000: Human monoclonal antibodies in Tris buffer containing IgG antibodies to Ro52, Rib-P and RNA Pol III, ready to use.
- EliA IgG/IgM/IgA Negative Control 250 or 2500/5000: Human blood preparation from healthy donors in PBS containing BSA, detergent and 0.095% sodium azide, ready to use.

EliA Method-Specific Reagents include:

- EliA Sample Diluent: PBS containing BSA, detergent and 0.095% sodium azide, ready to use.
- EliA IgG Conjugate 50 or 200: β-Galactosidase labeled anti-IgG (mouse monoclonal antibodies) in PBS containing BSA and 0.06% sodium azide, ready to use.
- EliA IgG Calibrator Strips: Human IgG (0, 4, 10, 20, 100, 600 µg/L) in PBS containing BSA, detergent and 0.095% sodium azide, ready to use.
- EliA IgG Curve Control Strips: Human IgG (20 µg/L) in PBS containing BSA, detergent and 0.095% sodium azide, ready to use.

- EliA IgG Calibrator Well: coated with mouse monoclonal antibodies, ready to use.

General Reagents are not included but required:

- Development Solution: 0.01% 4-methylumbelliferyl-β-D-galactoside, < 0.0010% preservative.
- Stop Solution: 4% sodium carbonate.
- Washing Solution Additive: detergent, preservative < 0.13%.
- Washing Solution Concentrate: phosphate buffer.

B Principle of Operation:

The EliA RNA Pol III is a semi-quantitative solid-phase fluoroimmunoassay for the determination of autoantibodies against RNA polymerase III. The EliA RNA Pol III test system is fully integrated and automated system which comprises of assay-specific reagents, EliA method-specific reagents, and general reagents.

The antigen (human recombinant RNA polymerase III) is immobilized on the EliA solid phase component (EliA Well). The EliA wells are molded cups comparable to excised wells from a microtiter plate. If present in the patient's specimen, antibodies to the RNA polymerase III bind to their specific antigen. After washing away non-bound antibodies, enzyme-labeled antibodies against human IgG antibodies (EliA IgG Conjugate) are added to form an antibody-conjugate complex. After incubation, non-bound conjugate is washed away, and the bound complex is incubated with a Development Solution. After stopping the reaction, the fluorescence in the reaction mixture is measured. The assay directly measures the amount of antibody of interest bound to the antigen coating the EliA well, therefore the higher the value of fluorescent signal detected by the instrument, the higher the amount of antibody bound and detected in the sample tested. To evaluate test results, the response for patient samples is compared directly to the response for calibrators.

V Substantial Equivalence Information:

A Predicate Device Name(s):

QUANTA Lite RNA POL III ELISA

B Predicate 510(k) Number(s):

K070066

C Comparison with Predicate(s):

Device & Predicate Device(s):	**K202541**	**K070066**
Device Trade Name	EliA RNA Pol III	QUANTA Lite RNA POL III ELISA
General Device Characteristic Similarities		

Device & Predicate Device(s):	K202541	K070066
Intended Use/ Indications for Use	EliA RNA Pol III is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to RNA polymerase III (RNA Pol III) in human serum as an aid in the diagnosis of systemic sclerosis (diffuse form) in conjunction with other laboratory and clinical findings. EliA RNA Pol III uses the EliA IgG method.	QUANTA Lite RNA Polymerase III ELISA is a semi-quantitative enzyme linked immunosorbent assay (ELISA) for the detection of IgG anti-RNA polymerase III antibodies in patient sera. The presence of these antibodies when considered in conjunction with other laboratory and clinical findings is an aid in the diagnosis of systemic sclerosis, (scleroderma), with increased incidence of skin involvement and renal crisis.
Methodology	ELISA	Same
Analyte	Autoantibodies to RNA polymerase III	Same
Sample matrix	Serum	Same
General Device Characteristic Differences		
Type of test	Automated semi-quantitative	Manual semi-quantitative
Antigen	Human recombinant RNA polymerase III protein	Recombinant RNA polymerase III fragment
Dilution	1:200	1:101
Detection	Fluorescence	Optical density (OD)
Conjugate	ß-Galactosidase conjugated anti-human IgG (mouse monoclonal antibodies)	Horseradish peroxidase conjugated anti-human IgG (goat)
Controls	EliA ANA 3 Positive Control and EliA IgG/IgM/IgA Negative Control	The RNA Pol III ELISA Low Positive, the RNA Pol III ELISA High Positive and the ELISA Negative Control
Calibration	6-point total IgG Calibration at concentrations of 0 – 4 – 10 – 20 – 100 – 600 µg/L	One-point calibration
Instrumentation	Phadia 250 and the E-modules of the Phadia 2500 and Phadia 5000 series	Microwell plate reader measuring OD at 450nm and 620nm
Cut-offs	Negative: <7 EliA U/mL Equivocal:7–10 EliA U/mL Positive: >10 EliA U/mL	Negative <20 Units Weak Positive 20–39 Units Moderate Positive 40–80 Units Strong Positive >80 Units

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures, Approved Guideline, Third Edition.
- CLSI EP06-Ed2, Evaluation of the Linearity of Quantitative Measurement Procedures.
- CLSI EP07, 3rd Edition, Interference Testing in Clinical Chemistry.
- CLSI EP09c 3rd Edition, Measurement Procedure Comparison and Bias Estimation Using Patient Samples.
- CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, Approved Guideline - Second Edition.
- CLSI EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory, Approved Guideline - Third Edition.
- CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents, Approved Guideline.
- CLSI EP37, 1st Edition, Supplemental Tables for Interference Testing in Clinical Chemistry.

VII Performance Characteristics (if/when applicable):

A Analytical Performance: All results presented below were within the Manufacturer's pre-determined acceptance criteria for each study.

1. Precision/Reproducibility:

Reproducibility:
The reproducibility of the EliA RNA Pol III was assessed by testing five serum samples using three lots of assay reagents on three Phadia 250 instruments. Each sample was tested in four replicates per run, one run per day for seven days using three lots of reagent to generate 84 replicates per sample on each instrument, or a total of 252 measurements. The results are summarized in the table below:

Sample	N	Mean (EliA U/mL)	Within-Run		Between-Run/Day		Between-Instrument		Between-Lot		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	252	3.1	0.1	2.3	0.1	2.2	0.1	3.0	0.1	1.5	0.2	4.6
2	252	7.5	0.1	1.7	0.1	1.4	0.2	2.3	0.1	0.7	0.3	3.3
3	252	9.1	0.2	2.0	0.2	1.9	0.1	1.5	0.0	0.5	0.3	3.2
4	252	19.2	0.4	2.1	0.3	1.7	0.1	0.7	0.2	0.9	0.6	2.9
5	252	171.9	6.6	3.8	4.0	2.3	3.4	2.0	3.8	2.2	9.2	5.3

Within-laboratory precision:
Within-laboratory imprecision of EliA RNA Pol III assay was evaluated by testing four serum samples using one lot of EliA RNA Pol III Well on one Phadia 250 instrument. Samples were tested in two replicates per run, two runs per day for 20 days, for a total of 80 replicates per sample. The results are shown in the following table:

Sample	N	Mean (EliA U/mL)	Within-Run		Between-Run		Between-Day		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	80	4.2	0.1	2.2	0.1	1.8	0.0	1.0	0.1	2.8
2	80	7.3	0.1	2.0	0.2	2.6	0.1	1.7	0.2	3.3
3	80	9.7	0.2	2.0	0.2	2.1	0.1	1.1	0.3	2.8
4	80	39.4	0.8	2.1	0.5	1.4	0.3	0.9	1.0	2.5

2. Linearity:

Four patient serum samples with following concentrations: 245.3 EliA U/mL, 172.5 EliA U/mL, 168.9 EliA U/mL, and 31.7 EliA U/mL were tested on Phadia 250. Four patient samples with following concentrations: 270.3 EliA U/mL, 184.0 EliA U/mL, 184.0 EliA U/mL, and 28.3 EliA U/mL were tested on Phadia 2500E. All samples were serially diluted with EliA Sample Diluent. Each dilution was tested in triplicate on one lot of the EliA RNA Pol III assay reagents and one set of system reagents on Phadia 250 and Phadia 2500E instruments. The ratios of observed/expected values were calculated. The observed values were graphed against the calculated values and a linear regression analysis was performed. The results are summarized in the tables below.

Results on Phadia 250:

Sample Number	Range [EliA U/mL]	Slope (95% CI)	Intercept (95% CI)	R^2	% Recovery
1*	0.8–31.7	0.99 (0.97–1.01)	-0.28 (-0.49– -0.07)	1.00	95.0–102.0
2	3.1–168.9	0.99 (0.98–1.01)	-0.09 (-0.28–0.11)	1.00	97.0–107.0
3	1.8–172.5	0.99 (0.98–1.00)	-0.48 (-0.48–1.24)	1.00	88.0–100.0
4	3.1–245.3	1.01 (0.99–1.02)	0.96 (-0.31–2.24)	1.00	102.0–110.0

*dilution below LoD was not included in analysis

Results on Phadia 2500E:

Sample Number	Range [EliA U/mL]	Slope (95% CI)	Intercept (95% CI)	R^2	% Recovery
1	0.7–28.3	1.02 (0.98–1.06)	0.19 (-0.32–0.70)	1.00	94.0–111.0
2	1.9–144.0	1.02 (0.98–1.06)	1.40 (-0.69–3.49)	1.00	100.0–114.0
3	3.0–184.0	1.00 (0.97–1.03)	-1.38 (-3.40–0.65)	1.00	88.0–102.0
4	3.0–270.3	1.01 (0.99–1.03)	-0.92 (-2.84–1.00)	1.00	90.0–104.0

The results support the linearity of the claimed measuring range (0.7–192.0 EliA U/mL) for EliA RNA Pol III.

Hook Effect/Over the Range Results:

Results above the upper limit of the measuring range are reported as ">192". No recommendations are made for dilution of samples outside measuring range in the Package Insert.

3. Analytical Specificity/Interference:

Comparison to Reference Sera:
CDC (Center for Disease Controls and Prevention) ANA Reference Panel Samples 1–12 were tested using one lot of EliA RNA Pol III assay reagents. All 12 sera samples found to be negative in the EliA RNA Pol III assay.

Endogenous Interference:
Three serum samples with following concentrations: 0.5 EliA U/mL (negative), 7 EliA U/mL (within the equivocal range), and 106 EliA U/mL (positive) were used for endogenous interference study. Additionally, three samples with following concentrations: 39 EliA U/mL, 11.7 EliA U/mL, and 11.2 EliA U/mL were tested for Rheumatoid factor interference. The samples were spiked with the different interfering substances or the corresponding substance-specific blank solution. For lipemic factor (ClinOleic) distilled water was used as the blank solution. The samples were tested in triplicate in two runs using one lot of EliA RNA Pol III Wells on Phadia 250. The quotient between serum sample spiked with interference substance and serum sample spiked with blank was calculated for each sample spiked with the interfering substance. The quotient between samples spiked with interference substance or blank were within the range of 0.90 – 1.10 The results are listed in the table below:

Compound	**No Interference up to Concentration**
Endogenous substance	
Bilirubin F	40 mg/dL
Bilirubin C	40 mg/dL
Hemoglobin	1000 mg/dL
Lipemic factor	2000 mg/dL
Rheumatoid factor	500 IU/mL

Exogenous Interference:
Three serum samples with following concentrations: 0.5 EliA U/mL (negative), 9 EliA U/mL (within the equivocal range), and 67 EliA U/mL (positive) were used for exogenous interference study. The samples were spiked with the different interfering substances or EliA Sample Diluent as the blank solution. The samples were tested in triplicate in two runs using one lot of EliA RNA Pol III Wells on Phadia 250. The quotient between serum sample spiked with interference substance and serum sample spiked with blank was calculated for each sample spiked with the interfering substance. The quotient between samples spiked with interference substance or blank were within the range of 0.90–1.10. The results are listed in the table below:

Compound	**No Interference up to Concentration**
Ibuprofen	21.9 mg/dL
Losartan	1.14 mg/dL
Hydroxychloroquine	0.23 mg/dL

Compound	No Interference up to Concentration
Azathioprine	0.26 mg/dL
Prednisone	0.01 mg/dL
Rituximab	109 mg/dL
Infliximab	26.4 mg/dL

4. Assay Reportable Range:

   The reportable range for the EliA RNA Pol III is 0.7–192.0 EliA U/mL.

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

   Traceability:

   There is no international reference standard that recognizes RNA Pol III. EliA IgG calibrators and EliA IgG Curve Controls are derived from a purchased immunoglobulin preparation (GAMMANORM, Biovitrum AB, Stockholm, Sweden). The EliA IgG calibrators are traceable via an unbroken chain of calibrations to the International Reference Preparation (IRP) 67/86 of Human Serum Immunoglobulins A, G and M from WHO. New batches of EliA IgG Calibrators are compared to a secondary standard (standardized with the IRP) or the IRP directly and adjusted accordingly to meet the correct concentration.

   Stability:

   The stability for the EliA RNA Pol III assay-specific reagent (EliA RNA Pol III Wells) were determined as follows:

   Kit stability (shelf-life): The shelf-life of the EliA RNA Pol III Wells was performed using Phadia 250 instrument. Three lots of the wells were stored at 2–8°C and tested at four timepoints (0, 7, 13, and 19 months) in triplicate determination. The wells were tested with five positive samples in triplicate determination and with nine negative samples in single determination with a full calibration curve. The EliA ANA 3 Positive Control and the EliA IgG/IgM/IgA Negative Control were additionally tested in triple determination. The shelf-life of the EliA RNA Pol III assay was determined to be 18 months stored at 2–8°C.

   Open-vial (in-use) stability: The stability of the EliA RNA Pol III Wells stored at 2–8°C after first opening of the foil bag was performed. The wells were tested at 4, 6 and 10 months in two identical test runs with three positive samples in triple determination and two negative samples in single determination. Each test run contained a full calibration curve. The in-use stability for the EliA RNA Pol III assay was determined to be 9 months at 2–8°C.

   On-board stability: The on-board stability of EliA RNA Pol III Wells was tested over six weeks using five samples (three positive and two negative) on the Phadia 250 instrument. The on-board stability EliA RNA Pol III assay was determined to be 28 days at 2–8°C.

6. Detection Limit:

Limit of blank (LoB), Limit of detection (LoD) and limit of quantitation (LoQ) of the EliA RNA Pol III assay were determined on both Phadia 250 and Phadia 2500E.

The LoB was determined from the measurement of four analyte-free (i.e., IgG-depleted sera) samples tested in five replicates per sample over three consecutive days using two lots of EliA RNA Pol III reagents on two instruments. The LoB was calculated as the 95th percentile for each lot (60 determinations per lot). LoB was determined as the higher value of these two lots for each type of instrument. The claimed LoB for EliA RNA Pol III assay is the greatest LoB across the two lots and both instrument types.

The LoD was determined by testing four low-level samples in five replicates per run per sample over three consecutive days using two lots of EliA RNA Pol III reagents on two instruments. The LoD for each lot was calculated based on 240 determinations with 120 blank and 120 low level replicates following recommendations of CLSI document EP17-A and with proportions of false positives (α) less than 5% and false negatives (β) less than 5%. The claimed LoD for EliA RNA Pol III assay is the greatest LoD across the two lots and both instrument types.

The LoQ was determined by testing four low-level samples on Phadia 2500E and five low-level samples on Phadia 250 in five replicates per sample over three days using two lots of EliA RNA Pol III reagents. The LoQ was defined to be the lowest concentration level that meets the within-laboratory imprecision of <20% for each lot. The greatest LoQ across the two lots and both instrument types were set as the claimed LoQ for EliA RNA Pol III assay.

The results are summarized in the table below:

Instrument	LoB EliA U/mL	LoD EliA U/mL	LoQ EliA U/mL
Phadia 250	0.0	0.2	0.4
E-module of the Phadia 2500E	0.0	0.1	0.3
The claim for both instrument types	**0.0**	**0.7**	**0.7**

7. Assay Cut-Off:

The assay cut-off and the equivocal range were established by testing a cohort consisting of 70 apparently healthy blood donors and 17 samples from systemic sclerosis (diffuse) patients on a Phadia 250 instrument. The assay cut-offs were set as follows:

Decision Point	Interpretation
< 7 EliA U/mL	Negative
7–10 EliA U/mL	Equivocal
> 10 EliA U/mL	Positive

In case of equivocal results, the manufacturer recommends retesting the patient after 8–12 weeks.

B Comparison Studies:

1. Method Comparison with Predicate Device:

One hundred ninety-three (193) serum samples with antibody concentrations covering the measuring range were analyzed with EliA RNA Pol III and the predicate QUANTA Lite RNA Pol III ELISA assay. Among them, 82 samples were found within the measuring ranges of both tests and used for the method comparison analysis. Positive percent agreement (PPA), negative percent agreement (NPA), and total agreement were calculated with equivocal results considered as negative or as positive, respectively. The results are summarized in the tables below:

EliA RNA Pol III: Equivocal results considered negative		**QUANTA Lite RNA POL III ELISA**		
		Positive: ≥ 20 Units	**Negative: < 20 Units**	**Total**
EliA RNA Pol III	**Positive: > 10 EliA U/mL**	38	0	38
	Negative: < 10 EliA U/mL	10	34	44
	Total	48	34	82

Equivocal results considered negative	**Agreement (%)**	**95% CI**
PPA	79.2	65.0–89.5
NPA	100.0	89.7–100.0
Total	87.8	78.7–94.0

EliA RNA Pol III: Equivocal results considered positive		**QUANTA Lite RNA POL III ELISA**		
		Positive: ≥ 20 Units	**Negative: < 20 Units**	**Total**
EliA RNA Pol III	**Positive: > 7 EliA U/mL**	42	0	42
	Negative: < 7 EliA U/mL	6	34	40
	Total	48	34	82

Equivocal results considered positive	**Agreement (%)**	**95% CI**
PPA	87.5	74.8–95.3
NPA	100.0	89.7–100.0
Total	92.7	84.8–97.3

2. Matrix Comparison:

Not applicable. Serum is the claimed sample type for this assay.

3. Instrument Comparison:

This study compared the performance of the Phadia 250 and Phadia 2500E instruments using the EliA RNA Pol III assay by evaluating 64 positive, 13 equivocal and 23 negative serum samples. The samples were analyzed in single determination on one Phadia 250 and one Phadia 2500E instrument each. The Passing-Bablok regression analysis showed the slope of 1.05 (95% CI: 1.04–1.07) and the intercept of -0.67 (95% CI: -1.13 – -0.44). The PPA, NPA, and total agreement were calculated with equivocal results considered as negative or as positive, respectively. The results are summarized in the tables below.

Positive/Negative Agreement if equivocal samples are considered positive.

	Agreement (%), (95% CI)
PPA	96.1, (89.0–99.2)
NPA	100.0, (85.2–100.0)
Total Agreement	97.0, (91.5–99.4)

Positive/Negative Agreement if equivocal samples are considered negative.

	Agreement (%), (95% CI)
PPA	96.9, (89.2–99.6)
NPA	100.0, (90.3–100.0)
Total Agreement	98.0, (93.0–99.8)

C Clinical Studies:

1. Clinical Sensitivity and Specificity:

A total of 596 clinically defined serum samples were included in the clinical evaluation for the EliA RNA Pol III. This validation cohort includes 132 samples from individuals diagnosed with diffuse systemic sclerosis, and 464 samples from patients with non-diffuse systemic sclerosis diseases/conditions.

The distribution of the cohort and the EliA RNA Pol III positivity rate for each clinical subgroup are summarized below:

Diagnostic groups	N	No (%) Positive EliA RNA Pol III
Systemic sclerosis (SSc), diffuse	132	30 (23.0%)
Non-SSc (diffuse) Specimens		
SSc, limited	91	1 (1.0%)
SSc, Raynaud Syndrome	13	0
Celiac disease	13	0
Crohn's disease	12	0
CTD* overlap non-MCTD**	10	1 (1.9%)
Dermatomyositis	4	0
Polymyositis	6	0
Grave's disease	12	0
Primary antiphospholipid syndrome	12	0
Primary biliary cirrhosis	21	0
Sjögren's syndrome	30	0
Systemic lupus erythematosus	16	0
Type 1 diabetes	12	0
Ulcerative colitis	11	0
Varied cancer	30	0
MCTD**	10	0
Rheumatoid arthritis	40	0
Hashimoto's disease	10	0
Bacterial infections	35	0
Viral infections	72	1 (1.0%)
Total	**464**	

*CTD: connective tissue disease
**MCTD: mixed connective tissue disease

Clinical sensitivity and specificity of the assay are summarized in the tables below:

EliA RNA Pol III – equivocal results evaluated as positive:

	Diagnosis		Total
	Systemic sclerosis (diffuse)	Disease Controls	
Positive test ≥ 7 EliA U/mL	33	4	37
Negative test < 7 EliA U/mL	99	460	559
Total	132	464	596

Sensitivity (95% CI): 25.0% (17.9%–33.3%)
Specificity (95% CI): 99.1% (97.8%–99.8%)

EliA RNA Pol III – equivocal results evaluated as negative:

	Diagnosis		Total
	Systemic sclerosis (diffuse)	Disease Controls	
Positive test ≥ 10 EliA U/mL	30	2	32
Negative test < 10 EliA U/mL	102	462	564
Total	132	464	596

Sensitivity (95% CI): 22.7% (15.9%–30.8%)
Specificity (95% CI): 99.6% (98.5%–99.9%)

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

Not applicable

D Clinical Cut-Off:

Same as assay cut-off.

E Expected Values/Reference Range:

The expected value in the normal population is negative. A panel of 568 serum samples from apparently healthy blood donors were collected from the Biobank at Phadia GmbH (Germany). The set consisted of the following age groups: ≤30 years (57 males, 57 females), 31-40 years (57 males, 57 females), 41-50 years (57 males, 57 females), 51-60 years (57 males, 57 females), >60 years (55 males, 57 females). The panel included 330 Caucasian samples, 238 multi-ethnicity donor samples (African Americans, Hispanics, and Asian blood donors). Two samples were found equivocal (7–10 EliA U/mL). The results are presented in the following table:

	Female					Male					Total
Age, years	≤30	31–40	41–50	51–60	>60	≤30	31–40	41–50	51–60	>60	
N	57	57	57	57	57	57	57	57	57	55	568
Median	<0.7	<0.7	<0.7	<0.7	<0.7	<0.7	<0.7	<0.7	<0.7	<0.7	<0.7
95th Percentile	1.5	1.6	1.3	1.6	1.5	1.8	1.5	1.4	1.4	1.4	1.6
99th Percentile	1.7	5.0	3.1	4.4	2.2	3.3	2.1	2.0	5.3	2.6	3.3

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.