510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K202067

B Applicant

Phadia AB

C Proprietary and Established Names

EliA SmD^{P}-S

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LKP	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 Sm protein (Sm) D component

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 SmD^{P}-S is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Sm in human serum and EDTA-plasma as an aid in the diagnosis of systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA SmD^{P}-S 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 E-module of the Phadia 2500 and Phadia 5000 series of instruments.

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 as separate units.

The EliA SmD^{P}-S Assay-Specific Reagents include:

- EliA SmD^{P}-S Wells: coated with a synthetic SmD_3 peptide – four carriers (16 wells each), 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.
- EliA ANA Positive Controls: Human blood preparation containing IgG antibodies to dsDNA, RNP, Sm, Ro, La, Scl-70, CENP and Jo-1 in PBS containing BSA, detergent and 0.095% sodium azide, 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.

General Reagents are not included but required:

- Development Solution: 0.01% 4-Methylumbelliferyl-β-D-galactoside, < 0.001% preservative.
- Stop Solution: 4% Sodium Carbonate.
- Washing Solution Additive: detergent, preservative < 0.13.
- Washing Solution Concentrate: phosphate buffer.

B Principle of Operation:

The EliA SmD^{P}-S Immunoassay is a semi-quantitative solid-phase fluoroimmunoassay for the determination of IgG autoantibodies against Sm. The EliA SmD^{P}-S test is fully integrated and automated system which comprises assay-specific reagents, EliA method-specific reagents, and general reagents.

The synthetic SmD_3 peptide 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 SmD_3 peptide 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 coated on 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):

EliA SmD^{P}

B Predicate 510(k) Number(s):

K132631

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device K202067	Predicate K132631
Device Trade Name	EliA SmD^{P}-S	EliA SmD^{P}
General Device Characteristic Similarities		
Intended Use / Indications for Use	EliA SmD^{P}-S is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Sm in human serum and EDTA-plasma as an aid in the diagnosis of systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA SmD^{P}-S uses the EliA IgG method.	EliA SmD^{P} is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Sm in human serum and plasma (EDTA, citrate) to aid in the diagnosis of systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA SmD^{P} uses the EliA IgG method on the instrument Phadia 100 and Phadia 250.

Assay Type	Solid phase fluoroimmunoassay	Same
Type of Test	Semi-quantitative	Same
Antigen	Synthetic SmD_3 peptide	Same
Detection antibody (conjugate)	ß-Galactosidase-coupled mouse anti-human IgG monoclonal antibodies	Same
Signal	Fluorescence	Same
Controls	Positive and negative	Same
Calibration	Calibration curve can be stored up to 28 days	Same
Calibrators	Set of six vials of human IgG at concentrations of 0, 4, 10, 20, 100, and 600 µg/L	Same
Cut-offs	Negative: < 7 EliA U/mL Equivocal: 7–10 EliA U/mL Positive: > 10 EliA U/mL	Same
General Device Characteristic Differences		
Solid Phase	Molded cups	Microwells
Instrumentation	Phadia 250, Phadia 2500E, Phadia 2500EE, Phadia 5000E, Phadia 5000E+E	Phadia 100 and 250
Sample matrix	Serum or EDTA-plasma	Serum, citrate-, EDTA-plasma
Sample Dilution	1:100	1:50
Coating Technology	Adsorptive coating of a SmD_3 peptide-polymer conjugate	Affinity-based coating of SmD_3 peptide
Shelf-life	18 months	24 months
Measuring range	0.8 – 310 EliA U/mL	0.8 – 480 EliA U/mL

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures, Approved Guideline, Third Edition.
- CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach, 2nd Edition.
- CLSI EP07-ED3, Interference Testing in Clinical Chemistry.
- CLSI EP09c-ED3, Measurement Procedure Comparison and Bias Estimation Using Patient Samples, June 2018.
- 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-ED1, Supplemental Tables for Interference Testing, September 2018.

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 SmD^{P}-S 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		Between-Instrument		Between-Lot		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	252	5.2	0.2	3.1	0.3	5.0	0.1	1.3	0.7	14.1	0.8	15.4
2	252	9.4	0.3	2.7	0.3	3.5	0.3	3.7	0.8	9.0	1.0	10.7
3	252	11.1	0.2	2.2	0.2	1.6	0.3	2.4	0.2	1.7	0.4	4.1
4	252	105.0	2.5	2.4	2.0	1.9	1.0	0.9	0.6	0.5	3.4	3.2
5*	251	273.0	12.5	4.6	3.2	1.2	16.6	6.1	14.9	5.5	25.8	9.4

*one data point is missing due to an instrument error.

Within-laboratory precision:
Within-laboratory imprecision of EliA SmD^{P}-S assay was evaluated by testing four serum samples using one lot of EliA SmD^{P}-S 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	4.3	0.1	2.3	0.1	1.7	0.1	1.2	0.1	3.1
2	80	7.3	0.2	2.7	0.0	0.0	0.2	2.2	0.3	3.5
3	80	9.9	0.2	2.3	0.2	1.9	0.1	0.9	0.3	3.2
4	80	110.0	3.0	2.7	1.8	1.7	1.3	1.2	3.8	3.4

Lot-to-lot imprecision:
Lot-to-lot imprecision was evaluated by testing three serum samples using three lots of EliA SmD^{P}-S Well and assay specific reagents and two lots of general reagents on one Phadia 250 instrument. Samples were tested in four replicates per run, one run per day for seven days to generate 28 data points per sample for each lot, and a total of 84 replicates per sample. The results are shown in the following table:

Sample	N	Mean (EliA U/mL)	Within-Run		Between-Run		Between-Lot		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	84	4.3	0.1	3.1	0.1	1.8	0.1	2.2	0.2	4.2
2	84	7.8	0.2	2.5	0.2	2.6	0.3	3.5	0.4	5.0
3	84	10.2	0.3	2.8	0.1	0.9	0.5	4.8	0.6	5.7

2. Linearity:

Three patient serum samples (with concentration at 310.8 EliA U/mL, 230.5 EliA U/mL, 9.7 EliA U/mL on Phadia 250, and 329.3 EliA U/mL, 205.6 EliA U/mL, 10.4 EliA U/mL on Phadia 2500E) were serially diluted with EliA Sample Diluent. Each dilution was tested in triplicate on one lot of the EliA SmD^{P}-S 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)	R2	% Recovery
1	3.2–310.8	1.0 (1.0–1.0)	0.6 (-1.1–2.2)	1.0	91.0–105.0
2	2.3–230.5	1.0 (1.0–1.0)	-0.3 (-0.9–0.3)	1.0	94.0–102.0
3	0.5–9.7	1.0 (1.0–1.0)	-0.2 (-0.4–0.0)	1.0	81.0–100.0

Results on Phadia 2500E:

Sample Number	Range [EliA U/mL]	Slope (95% CI)	Intercept (95% CI)	R2	% Recovery
1	3.0–329.3	1.0 (1.0–1.0)	-0.2 (-3.3– -0.8)	1.0	85.0–100.0
2	1.8–205.6	1.0 (1.0–1.1)	0.2 (-4.0–4.3)	1.0	88.0–112.0
3	0.6–10.4	1.0 (1.0–1.1)	0.0 (-0.3–0.3)	1.0	92.0–117.0

The results support the linearity of the claimed measuring range (0.8–310 EliA U/mL) for EliA SmD^{P}-S.

Hook Effect/Over the Range Results:

Results above the upper limit of the measuring range are reported as ">310". No recommendations are made for dilution of samples above measuring range in the package insert.

3. Analytical Specificity/Interference:

Comparison to Reference Sera:
CDC (Center for Disease Controls and Prevention) ANA Reference Panel containing 12 sera samples and 2002 AMLI (The Association of Medical Laboratory Immunologists) Consensus Reference Panel (RP2002) containing 10 samples were tested using one lot of EliA SmD^{P}-S assay reagents. Among the 12 sera in CDC Panel, the only sera that was known to be positive

for Sm was found to be reactive in the EliA SmD^{P}-S assay. Among the 10 sera in AMLI Panel, none of samples which were known to be positive for SmB, SmB', SmE, and SmF was detected by the EliA SmD^{P}-S assay.

Endogenous and Exogenous Interference:
Three serum samples with concentration at 3.0 EliA U/mL (negative), around 7 EliA U/mL (within the equivocal range), and > 200 EliA U/mL (high positive) were spiked with the different interfering substances or blank solution. The samples were tested in triplicate in two runs using one lot of EliA SmD^{P}-S Wells on Phadia 250. The % recovery for each sample spiked with the interfering substance was calculated by comparing its result to that of the corresponding control sample with blank solution. No significant interferences were observed in the study up to the concentrations listed in the table below:

Compound	**No Interference up to Concentration**
Endogenous substance	
Bilirubin F	19.2 mg/dL
Bilirubin C	20.1 mg/dL
Hemoglobin	501 mg/dL
Lipemic factor	1g/dL
Rheumatoid factor	505 IU/mL
Exogenous substance	
Ibuprofen	21.9 mg/dL
Losartan	1.14 mg/dL
Hydroxychloroquine	0.23 mg/dL
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 SmD^{P}-S is 0.8–310 EliA U/mL.

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

Traceability:
There is no international reference standard that recognizes the SmD_3 peptide. The EliA IgG Calibrators and EliA IgG Curve Controls are derived from a purchased immunoglobulin preparation. The IgG calibrators are traceable via 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 IgG calibrators are compared to a secondary standard (standardized with the IRP) or to the IRP directly and adjusted accordingly to meet the correct concentration.

Stability:
The stability for the EliA SmD^{P}-S assay-specific reagent (EliA SmD^{P}-S Wells) were determined as follows:

Kit stability (shelf-life): The shelf-life of the EliA SmD^{P}-S 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 four positive samples in triplicate determination and with nine negative samples in single determination with a full calibration curve. The EliA ANA Positive Control and the EliA IgG/IgM/IgA Negative Control were additionally tested in triple determination. The shelf-life of the EliA SmD^{P}-S assay was determined to be 18 months stored at 2–8°C.

Open-vial (in-use) stability: The stability of the EliA SmD^{P}-S Wells stored at 2–8°C after first opening of the foil bag was performed. The wells were tested at 4, 7 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 SmD^{P}-S assay was determined to be 9 months at 2–8°C.

On-board stability: The on-board stability of EliA SmD^{P}-S wells was tested over 4 weeks using six samples (two positive, two equivocal and two negative) on the Phadia 250 instrument. The on-board stability EliA SmD^{P}-S 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 SmD^{P}-S assay were determined on both Phadia 250 and Phadia 2500E.

The LoB was determined from the measurement of four analyte-free samples tested in quadruplicate per sample over six days using two lots of EliA SmD^{P}-S reagents on two instruments. The LoB was calculated as the 95th percentile for each lot (48 determinations). LoB was determined as the higher value of these two lots for each type of instrument. The claimed LoB for EliA SmD^{P}-S assay is the greatest LoB across the two lots and both instrument types.

The LoD was determined by testing four low-level samples in quadruplicate per sample over six days using two lots of EliA SmD^{P}-S reagents on two instruments. The LoD was calculated based on 192 determinations with 96 blank and 96 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 SmD^{P}-S assay is the greatest LoD across the two lots and both instrument types.

The LoQ was determined by testing four low-level samples in quadruplicate per sample over six days using two lots of EliA SmD^{P}-S reagents on two instruments. 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 SmD^{P}-S assay.

The results are summarized in the table below:

Instrument	LoB EliA U/mL	LoD EliA U/mL	LoQ EliA U/mL
Phadia 250	0.3	0.5	0.7
E-module of the Phadia 2500E	0.4	0.7	0.8
The claim for both instrument types	**0.4**	**0.7**	**0.8**

7. Assay Cut-Off:

The assay cut-off and the equivocal range were established by testing a cohort consisting of 200 clinically defined disease control samples 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:

Six hundred twenty-eight (628) serum samples with antibody concentrations covering the measuring range were analyzed with EliA SmD^P-S and the predicate EliA SmD^P. Among them, 460 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:

		Predicate EliA SmD^P			
		Positive: > 10 EliA U/mL	**Equivocal: 7 – 10 EliA U/mL**	**Negative: < 7 EliA U/mL**	**Total**
EliA SmD^P-S	**Positive: > 10 EliA U/mL**	169	8	1	178
	Equivocal: 7 – 10 EliA U/mL	13	11	6	30
	Negative: < 7 EliA U/mL	2	14	236	252
	Total	187	25	243	460

Equivocal results considered negative	Agreement (%)	95% CI
PPA	91.8	86.9–95.4
NPA	96.7	93.9–98.5
Total	94.8	92.3–96.6

Equivocal results considered positive	Agreement (%)	95% CI
PPA	92.6	88.3–95.7
NPA	97.1	94.2–98.8
Total	95.0	94.2–98.8

2. Matrix Comparison:

A total of 93 matched samples from 93 individual subjects with antibody concentrations covering the measuring range were collected in serum and K3-EDTA plasma tubes. All samples were run in single determination on a Phadia 250 instrument using one lot of EliA SmD^{P}-S reagents. A Passing-Bablok analysis was performed to evaluate the comparability between matrices and the results are summarized in the table below:

	N	Range tested (EliA U/mL)	Slope (95% CI)	Intercept (95% CI)	R^2
Serum vs. EDTA plasma	93	1.2–278.7	0.99 (0.96–1.02)	0.13 (-0.12–0.38)	1.00

The plasma preparation with heparin is not recommended because heparin interferes with the measurement of Sm antibodies. The package insert of the EliA SmD^{P}-S list the following limitation: "*Heparin can suppress SmD antibody reaction. Some EliA SmD^{P}-S results in the equivocal / low positive range obtained from Li-heparin plasma samples may be underestimated*."

3. Instrument Comparison:

This study compared the performance of the Phadia 250 and Phadia 2500E instruments using the EliA SmD^{P}-S assay by evaluating 105 positive, 15 equivocal and 14 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 1.01 (95% CI: 0.90–1.10) and the intercept close to zero (0.73, 95% CI: 1.20– -0.36). 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	97.5% (92.9–99.5)
NPA	100% (76.8–100)
Total Agreement	97.8% (93.6–99.5)

Positive/Negative Agreement if equivocal samples are considered negative.

	Agreement (%), (95% CI)
PPA	96.2% (90.5–99.0)
NPA	96.6% (82.2–99.9)
Total Agreement	96.3% (91.5–98.8)

C Clinical Studies:

1. Clinical Sensitivity and Specificity:

A total of 328 clinically defined serum samples were included in the clinical evaluation for the EliA SmD^{P}-S. This validation cohort includes 104 samples from individuals diagnosed with SLE, and 224 samples from patients with non-SLE diseases/conditions (mixed connective tissue disease, Sjögren's syndrome, scleroderma, polymyositis/dermatomyositis, rheumatoid arthritis, Graves' disease, Hashimoto's disease, bacterial infections, and viral infections). Clinical sensitivity and specificity of the assay are summarized in the tables below:

EliA SmD^{P}-S – equivocal results evaluated as positive:

	Diagnosis		Total
	SLE	**Controls**	
Positive test ≥ 7 EliA U/mL	19	3	22
Negative test < 7 EliA U/mL	85	221	306
Total	104	224	328

Sensitivity (95% CI): 18.3% (11.4%–27.1%)
Specificity (95% CI): 98.7% (96.1%–99.7%)

EliA SmD^{P}-S – equivocal results evaluated as negative:

	Diagnosis		Total
	SLE	**Controls**	
Positive test > 10 EliA U/mL	19	1	20
Negative test ≤ 10 EliA U/mL	85	223	308
Total	104	224	328

Sensitivity (95% CI): 18.3% (11.4%–27.1%)
Specificity (95% CI): 99.6% (97.5%–100%)

The distribution of the cohort and the SmD^{P} positivity rate for each clinical subgroup are summarized below:

Diagnostic groups	n	No (%) Positive EliA SmD^P-S
Systemic lupus erythematosus	104	19 (18.3%)
Non-SLE Specimens		
Mixed connective tissue disease	22	0
Sjögren's syndrome	28	0
Scleroderma	32	0
Polymyositis/Dermatomyositis	10	0
Rheumatoid arthritis	52	1 (1.9%)
Graves' disease	10	0
Hashimoto's disease	10	0
Bacterial infections	30	0
Viral infections	30	0
Total	328	

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 632 serum samples from apparently healthy blood donors were collected from the Biobank at Phadia GmbH (Germany). The set consisted from age ≤ 30 years (64 males, 64 females), 31-40 years (64 males, 64 females), 41-50 years (64 males, 64 females), 51-60 years (63 males, 62 females), >60 years (62 males, 61 females). The panel included 400 samples from Caucasian origin, 80 samples from African Americans, 80 samples from Hispanics, and 72 samples from Asian blood donors. One sample was found equivocal (7–10 EliA U/mL), one sample low positive, and one sample was found positive (>10 EliA U/mL). The results are presented in the following table:

	Male					Female					Total
Age, years	≤30	31–40	41–50	51–60	>60	≤30	31–40	41–50	51–60	>60	
N	64	64	64	63	62	64	64	64	62	61	632
Min	1.1	0.9	1.0	1.0	1.2	1.1	1.1	0.9	<0.7	0.8	<0.7
Max	3.2	4.9	4.2	3.4	9.3	10.4	5.5	4.6	11.5	5.1	11.5
Mean	1.9	2.1	2.0	2.1	2.3	2.4	2.3	1.9	2.1	1.7	2.1
Median	1.8	1.9	1.8	2.1	2.0	1.9	1.9	1.7	1.8	1.6	1.8
95th Percentile	2.8	3.4	3.0	2.8	4.3	4.0	4.7	3.2	3.5	3.1	3.6
99th Percentile	3.0	4.8	3.7	3.1	6.7	6.7	5.2	4.2	7.3	4.3	5.0

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.