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

I Background Information:

A 510(k) Number

K243575

B Applicant

Biokit, S.A.

C Proprietary and Established Names

ARCHITECT HSV-2 IgG, ARCHITECT HSV-2 IgG Calibrator, ARCHITECT HSV-2 IgG Controls

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
MYF	Class II	21 CFR 866.3305 - Herpes Simplex Virus Serological Assays	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

Clearance of a new device.

B Measurand:

Herpes Simplex HSV-2 IgG antibodies.

C Type of Test:

Chemiluminescent microparticle immunoassay (CMIA).

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The ARCHITECT HSV-2 IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of specific IgG antibodies to herpes simplex virus type 2 (HSV-2) in human serum (collected in serum and serum separator tubes) and plasma (collected in dipotassium EDTA, lithium heparin, and lithium heparin plasma separator tubes) on the ARCHITECT i System.

The ARCHITECT HSV-2 IgG assay is to be used for testing sexually active adults or expectant mothers to aid in the presumptive diagnosis of HSV-2 infection. The test results may not determine the state of active lesions or associated disease manifestations, particularly for primary infection. The predictive value of a reactive or nonreactive result depends on the prevalence of HSV-2 infection in the population and the pre-test likelihood of HSV-2 infection.

NOTE: The performance of the ARCHITECT HSV-2 IgG assay has not been established for use in the pediatric population, for neonatal screening, or for testing immunocompromised or immunosuppressed patients. The assay has not been FDA cleared or approved for screening blood or plasma donors.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

For use with the ARCHITECT i2000SR System.

IV Device/System Characteristics:

A Device Description:

The ARCHITECT HSV-2 IgG assay is an automated, two-step immunoassay for the qualitative detection of IgG antibodies to HSV-2 in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology.

The kit contains different components: Reagent (microparticles, conjugate and assay diluent), Calibrator, and external Controls (reactive and nonreactive).

Interpretation of results

The cutoff is 1.00 S/CO.

The ARCHITECT HSV-2 IgG test result should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.

S/CO	Interpretation
< 1.00	Nonreactive
≥ 1.00	Reactive

B Principle of Operation:

The specimen is incubated with the assay diluent and microparticles which contain specific recombinant-gG2 antigen. Antigen-antibody complexes will form if anti-HSV-2 antibodies are present in the sample. The mixture is washed, and the unbound material is removed. The
conjugate contains monoclonal anti-human IgG labeled with acridinium-labeled, and is used to detect HSV-2 IgG in the patient specimen. Anti-human IgG acridinium-labeled conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added.

The resulting chemiluminescent reaction is measured as a relative light unit (RLU). There is a direct relationship between the amount of HSV-2 IgG detected in the sample and the RLU measured by the system optics.

The presence or absence of HSV-2 IgG in the sample is determined by comparing the chemiluminescent RLU measured to the cutoff RLU determined from an active calibration.

C Instrument Description Information:

1. Instrument Name:

   ARCHITECT i2000SR System

2. Specimen Identification:

Specimen Types	Collection Tubes
Serum	Serum Serum separator
Plasma	Dipotassium EDTA Lithium heparin Lithium heparin separator

V Substantial Equivalence Information:

A Predicate Device Name(s):
HSV-1 & HSV-2 Differentiation Immunoblot IgG

B Predicate 510(k) Number(s):
K000238

C Comparison with Predicate(s):

Device & Predicate Device(s):	Predicate Device	Candidate Device
	K000238	K243575
Device Trade Name	HSV-1 & HSV-2 Differentiation Immunoblot IgG	ARCHITECT HSV-2 IgG, ARCHITECT HSV-2 IgG Calibrator, ARCHITECT HSV-2 IgG Controls
General Device Characteristic Similarities		
Intended Use/Indications For Use	MRL Diagnostics' HSV-1 & HSV-2 Differentiation Immunoblot IgG test is intended for qualitatively detecting the presence or absence of human IgG class antibodies to HSV-1 and HSV-2 in human sera. The test is indicated for testing sexually active adults or expectant mothers for aiding in the presumptive diagnosis of HSV-1 and HSV-2 infection. The predictive value of a positive or negative result depends on the population's prevalence and pretest likelihood of HSV-1 and HSV-2 infection. The performance of this assay has not been established for use in a pediatric population, for neonatal screening, for testing of immunocompromised patients, for use by a point of care facility or for use with automated equipment.	The ARCHITECT HSV-2 IgG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of specific IgG antibodies to herpes simplex virus type 2 (HSV-2) in human serum (collected in serum and serum separator tubes) and plasma (collected in dipotassium EDTA, lithium heparin, and lithium heparin plasma separator tubes) on the ARCHITECT i System. The ARCHITECT HSV-2 IgG assay is to be used for testing sexually active adults or expectant mothers to aid in the presumptive diagnosis of HSV-2 infection. The test results may not determine the state of active lesions or associated disease manifestations, particularly for primary infection. The predictive value of a reactive or nonreactive result depends on the prevalence of HSV-2 infection in the population and the pre-test likelihood of HSV-2 infection. NOTE: The performance of the ARCHITECT HSV-2 IgG assay has not been established for use in the pediatric population, for neonatal screening, or for testing immunocompromised or immunosuppressed patients. The assay has not been FDA cleared or approved for screening blood or plasma donors.
Analyte	Human IgG class antibodies to HSV-1 and HSV-2	Human IgG antibodies to HSV-2

Test type	Qualitative	Same
Regulation Section	21 CFR 866.3305	Same
Classification	Class II Special Controls	Same
General Device Characteristic Differences		
Product Code	LGC	MYF
Technology	Nitrocellulose immunoblot	Chemiluminescent Immunoassay
Sample type	Human serum	Human serum (collected in serum and serum separator tubes) and plasma (collected in dipotassium EDTA, lithium heparin, and lithium heparin plasma separator tubes)
Interpretation	Visually evaluate multiple bands	The cutoff is 1.00 S/CO. <1.00 S/CO = Nonreactive ≥1.00 S/CO = Reactive

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline -Third Edition (2014).
- CLSI EP07 Interference Testing in Clinical Chemistry; Approved Guideline-Third Edition (2018).
- CLSI EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples. 3rd Edition (2018)
- CLSI EP12-A2 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition (2008).
- CLSI EP25-A Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline (2009).
- IEC/EN 61010-1:2010 (3rd Ed) Safety Requirements for Electrical Equipment for Measurement Control and Laboratory Use-Part 1
- CLSI I/LA21-A2 Clinical Evaluation of Immunoassays; Approved Guideline - Second Edition
- Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

a. Within-Laboratory Precision (20-Day).
A within laboratory precision study was performed using 3 lots of the ARCHITECT HSV-2 IgG reagents, 3 lots of the ARCHITECT HSV-2 IgG Calibrator, 1 lot of the ARCHITECT HSV-2 IgG controls, and 1 ARCHITECT i200SR instrument. The

performance of the 3 lots of the ARCHITECT HSV-2 IgG reagents is shown in the following tables.

Table 1: 20-Day Within-Laboratory Precision.

Sample	n	Mean (S/CO)	Within-Run (Repeatability)		Between-Lot[a]		Within-Laboratory[b]	
			SD	%CV	SD	%CV	SD	%CV
Negative Control	240	0.30	0.009	N/A	0.007	N/A	0.012	N/A
Positive Control	240	3.01	0.075	2.5	0.081	2.7	0.117	3.9
Serum Panel 1	240	0.95	0.029	N/A	0.015	N/A	0.040	N/A
Serum Panel 2	240	1.60	0.037	2.3	0.096	6.0	0.109	6.8
Serum Panel 3	244[c]	2.47	0.093	3.7	0.270	10.9	0.286	11.6
Plasma Panel 1	240	1.03	0.028	2.7	0.004	0.4	0.034	3.3
Plasma Panel 2	240	1.81	0.047	2.6	0.089	4.9	0.103	5.7
Plasma Panel 3	240	2.91	0.071	2.4	0.093	3.2	0.126	4.3

N/A = Not applicable
[a] Calibrator and reagent lots are confounded.
[b] Includes within-run, between-run, between-day, and between-lot variability.
[c] Serum Panel 3 was tested for one additional day.

b. Within-Laboratory Precision (12-Day).

An additional within-laboratory precision study was conducted using samples with higher analyte levels, using 2 lots of the ARCHITECT HSV-2 IgG reagents, 1 lot of the ARCHITECT HSV-2 IgG Calibrator, and 1 ARCHITECT i2000SR instrument.

Table 2: 12-Day Within-Laboratory Precision.

Sample	n	Mean (S/CO)	Within-Run (Repeatability)		Between-Lot		Within-Laboratory[a]	
			SD	%CV	SD	%CV	SD	%CV
Serum Panel 4	96	7.14	0.274	3.8	0.125	1.7	0.372	5.2
Serum Panel 5	96	14.73	0.519	3.5	0.099	0.7	0.680	4.6
Plasma Panel 4	96	7.85	0.312	4.0	0.000	0.0	0.354	4.5
Plasma Panel 5	96	14.90	0.578	3.9	0.000	0.0	0.745	5.0

[a] Includes within-run, between-run, between-day, and between-lot variability.

c. Reproducibility.

A reproducibility study was conducted at 3 testing sites using one lot of the ARCHITECT HSV-2 IgG reagents, 1 lot of the ARCHITECT HSV-2 IgG Calibrator, 1 lot of the ARCHITECT HSV-2 IgG controls, and 1 ARCHITECT i2000SR instrument, over 5 days.

Table 3: Reproducibility.

		Mean (S/CO)	Repeatability		Between-Run		Between-Day		Between-Site/Instrument		Reproducibility[a]	
Sample	**N**		**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Negative Control	90	0.29	0.01	N/A	0.00	N/A	0.00	N/A	0.01	N/A	0.02	N/A
Positive Control	90	2.98	0.07	2.3	0.04	1.2	0.04	1.4	0.13	4.3	0.16	5.2
Serum Panel 1	90	0.89	0.02	N/A	0.01	N/A	0.01	N/A	0.02	N/A	0.04	N/A
Serum Panel 2	90	1.56	0.05	3.5	0.00	0.0	0.01	0.7	0.03	2.0	0.06	4.0
Serum Panel 3	90	2.52	0.06	2.2	0.03	1.3	0.02	1.0	0.08	3.3	0.11	4.3
Plasma Panel 1	90	0.96	0.03	N/A	0.01	N/A	0.02	N/A	0.03	N/A	0.05	N/A
Plasma Panel 2	90	1.76	0.05	2.8	0.00	0.0	0.03	1.7	0.07	4.0	0.09	5.2
Plasma Panel 3	90	2.82	0.09	3.3	0.00	0.0	0.00	0.0	0.12	4.3	0.15	5.4

[a] Includes repeatability (within-run), between-run, between-day, and between-instrument/site variability.

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

a. Interference

Potentially Interfering Endogenous Substances and Potentially Interfering Drugs. The ARCHITECT HSV-2 IgG assay was evaluated for potential interference of endogenous and exogenous (drugs) substances using HSV-2 IgG nonreactive and low reactive samples.

Less than 10% absolute difference for reactive HSV-2 IgG samples and less than 0.10 S/CO absolute difference for nonreactive HSV-2 IgG samples were observed at the following concentrations of potentially interfering substances.

Table 4: Potentially Interfering Endogenous Substances.

Potentially Interfering Endogenous Substance	Potential Interferent Concentration	
	Default Units	**Alternate Units**
Bilirubin (Conjugated)	40 mg/dL	475 µmol/L
Bilirubin (Unconjugated)	40 mg/dL	684 µmol/L
Hemoglobin	1000 mg/dL	10 g/L
Triglycerides	1500 mg/dL	16.94 mmol/L
Total Protein	15 g/dL	150 g/L
Serum Albumin	6 g/dL	60 g/L
Total Cholesterol	400 mg/dL	10.3 mmol/L

Table 5: Potentially Interfering Drugs.

	Potential Interferent Concentration	
Potentially Interfering Drug	**Default Units**	**Alternate Units**
Acetaminophen	15.6 mg/dL	1030 µmol/L
Acetylsalicylic acid	3.00 mg/dL	167 µmol/L
Acyclovir	6.6 mg/dL	293 µmol/L
Ampicillin	7.5 mg/dL	215 µmol/L
Ascorbic acid	5.25 mg/dL	298 µmol/L
Biotin	4250 ng/mL	17.3 µmol/L
Calcium dobesilate	6.00 mg/dL	144 µmol/L
Cefoxitin	660 mg/dL	15 500 µmol/L
Cyclosporine	0.180 mg/dL	1.50 µmol/L
Doxycycline	1.80 mg/dL	40.5 µmol/L
Famvir	0.25 mg/L	0.778 µmol/L
Ibuprofen	21.9 mg/dL	1060 µmol/L
Levodopa	0.750 mg/dL	38.0 µmol/L
Methyldopa	2.25 mg/dL	107 µmol/L

Potentially Interfering Drug	Potential Interferent Concentration	
	Default Units	Alternate Units
Metronidazole	12.3 mg/dL	719 µmol/L
N-Acetylcysteine	15.0 mg/dL	920 µmol/L
Phenylbutazone	32.1 mg/dL	1040 µmol/L
Rifampicin	4.8 mg/dL	58.3 µmol/L
Sodium heparin	330 units/dL	N/A
Theophylline	6.00 mg/dL	333 µmol/L
Valacyclovir	3 mg/L	8.314 µmol/L

b. Potential Cross-Reactivity

The ARCHITECT HSV-2 IgG assay was evaluated for potential cross-reactivity using specimens from individuals containing antibodies to other microorganisms or with medical conditions unrelated to HSV-2 infection. The data are summarized in the following table.

Table 6: Potential Cross-Reactivity.

Category	n	ARCHITECT HSV-2 IgG		False Positive Rate (%)
		Reactive	Nonreactive	
Anti-dsDNA autoantibodies	8	1	7	12.50
Antinuclear antibody	12	0	12	0
Candida albicans	13	0	13	0
Chlamydia trachomatis	10	0	10	0
Cytomegalovirus (IgG)	11	0	11	0
Elevated IgG	12	1	11	8.33
Elevated IgM	9	0	9	0
Epstein-Barr virus (IgG)	12	0	12	0
Gardnerella vaginalis	10	1	9	10.00
HAMA	8	0	8	0
Hepatitis A virus IgG	10	0	10	0
Hepatitis B virus IgG	12	0	12	0
Hepatitis C virus IgG	12	0	12	0

Category	n	ARCHITECT HSV-2 IgG		False Positive Rate (%)
		Reactive	Nonreactive	
HSV-1 IgG	6	0	6	0
Human herpesvirus-6 IgG	13	1	12	7.69
Human herpesvirus-8 IgG	10	2	8	20.00
Human immunodeficiency virus IgG	11	0	11	0
Human papillomavirus IgG	12	0	12	0
Influenza vaccine recipients	10	0	10	0
Monoclonal hyperimmunoglobulinemia	13	0	13	0
Mycoplasma pneumoniae	5	0	5	0
Multiparous females	3	0	3	0
Neisseria gonorrhea	6	0	6	0
Parvovirus B19 IgG	13	2	11	15.38
Pregnant females all trimesters	6	0	6	0
Rheumatoid factor (RF)	10	1	9	10.00
Rubella virus IgG	12	0	12	0
Streptococcus	9	0	9	0
Toxoplasma gondii	10	1	9	10.00
Treponema pallidum	12	0	12	0
Varicella-zoster virus IgG	13	0	13	0

4. Assay Reportable Range:

   Not applicable.

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

   Kit real-Time Stability Studies

   The data support the following storage conditions for the ARCHITECT HSV-2 IgG assay:

   Table 7: ARCHITECT HSV-2 IgG storage conditions.

Stability Study	Claims
Reagent On-Board	Up to 30 days
Reagent Unopened Shelf Life	10 months at 2-8°C
Reagent In-Use/Opened	10 months at 2-8°C
Calibrator Unopened Shelf-Life	12 months at 2-8°C
Calibrator In-Use/Opened	12 months at 2-8°C
Controls Unopened Shelf Life	12 months at 2-8°C
Controls In-Use/Opened	12 months at 2-8°C

Specimens Stability

The stability of specimens stored under different conditions was evaluated by testing a panel of natural and contrived samples (including Serum, Serum Separator Tube (SST), Dipotassium EDTA plasma, Lithium Heparin plasma and Lithium heparin separator on the ARCHITECT HSV-2 IgG assay. The data support the following specimen storage conditions: 1 month frozen (≤-20°C), 14 days refrigerated (2 to 8°C) off the clot, 7 days refrigerated (2 to 8°C) on the clot, 48 hours at room temperature (15 to 30°C) and up to 3 freeze/thaw cycles.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   A study to establish the ARCHITECT HSV-2 IgG assay cutoff was performed using 505 serum samples (271 reactive, 228 nonreactive, and 6 equivocal for HSV-2 IgG antibodies).

   Receiver-Operating Characteristic (ROC) curve analysis was performed. The optimal cut-off of 1.00 S/CO was selected and validated in the method comparison study (clinical agreement study).

8. Accuracy (Instrument):

   N/A

9. Carry-Over:

The ARCHITECT HSV-2 IgG assay is not susceptible to within-assay sample carryover.

10. Class-specificity:

    The Class specificity was supported for the ARCHITECT HSV-2 IgG assay demonstrating that the ARCHITECT HSV-2 IgG assay specifically detects IgG class immunoglobulin.

B Comparison Studies:

1. Method Comparison with Predicate Device:

A multi-center clinical study was conducted to evaluate the clinical performance of the ARCHITECT HSV-2 IgG assay. Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were determined comparing the performance of the ARCHITECT HSV-2 IgG assay to a composite comparator method comprised of 3 commercially available anti-HSV-2 IgG assays where a 2 out of 3 approach was followed to determine the final composite comparator method result.

A total of 915 specimens, which included sexually active individuals and pregnant females, were collected prospectively within the United States and tested at 3 independent external laboratories.
The PPA and NPA results are summarized in the following tables.

Table 8. Clinical performance of the ARCHITECT HSV-2 IgG in the Sexually Active Population (N=618).

Sexually Active Population		**Composite Comparator Method**		
		Positive	**Equivocal**	**Negative**
ARCHITECT HSV-2 IgG	**Reactive**	223	0	12
	Nonreactive	5	3	375
	Total	228	3	387
		PPA= 96.54% (223/231); **95%CI**= 93.32% to 98.24%		**NPA**= 96.90% (375/387); **95% CI**= 94.66% to 98.22%

Table 9. Clinical performance of the ARCHITECT HSV-2 IgG in the Pregnant Population (N=297).

Pregnant Population		**Composite Comparator Method**		
		Positive	**Equivocal**	**Negative**
ARCHITECT HSV-2 IgG	**Reactive**	78	0	3
	Nonreactive	4	0	212
	Total	82	0	215
		PPA= 95.12% (78/82); **95%CI**= 88.12% to 98.09%		**NPA**= 98.60% (212/215); **95% CI**= 95.98% to 99.52%

2. Tube Types Matrix Comparison:

Sixty-one (61) sets of matched reactive and nonreactive samples of different matrices (serum, serum separator tube, dipotassium EDTA plasma, lithium heparin plasma,

lithium heparin separator) from commercial sources were evaluated with the ARCHITECT HSV-2 IgG assay on the ARCHITECT i2000SR instrument for equivalency. The samples were analyzed by linear regression using serum as the comparator matrix.

Table 10. Regression analysis on matrix equivalence.

Tube (y) vs. Serum (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum separator tube	y = 1.03x – 0.0350 S/CO	0.50-54.76 S/CO	61	0.998
Plasma, dipotassium EDTA	y = 1.02x + 0.0079 S/CO	0.56-54.02 S/CO	61	0.997
Plasma, lithium heparin	y = 1.03x – 0.0029 S/CO	0.55-54.77 S/CO	61	0.996
Plasma, lithium heparin separator	y = 1.00x + 0.0343 S/CO	0.56-54.55 S/CO	61	0.997

[a] Number of samples tested
[b] Correlation coefficient

The following tube types are acceptable for use with the ARCHITECT HSV-2 IgG assay:

- Serum
- Serum separator
- Plasma (dipotassium EDTA, Lithium heparin, Lithium heparin separator)

C Clinical Agreement Study:

1. Clinical Sensitivity:
   Not applicable

2. Clinical Specificity
   Not Applicable.

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

   CDC Panel agreement

   The CDC panel consisted of 2 aliquots each of 50 serum samples with unknown HSV-2 status for a total of 100 blind characterized samples.

   The ARCHITECT HSV-2 IgG assay demonstrated 100% Positive Percent Agreement (PPA) for reactive samples (30/30) and 97.14% Negative Percent Agreement (NPA) for nonreactive samples (68/70) in concordance with the results provided by the CDC.

   Low Prevalence Specificity

   An additional study was performed to determine the specificity of the ARCHITECT HSV-2 IgG assay using 139 serum specimens from 16-19 year old individuals in a non-sexually transmitted disease setting within the US. The ARCHITECT HSV-2 IgG assay

demonstrated a NPA of 98.48% (130/132) with a 95% two-sided confidence interval (CI) of 94.64% to 99.58 % by Wilson score.

D Clinical Cut-Off:

See Assay Cut-Off

E Expected Values/Reference Range:

Representative performance data are provided in this section. Results obtained in individual laboratories may vary considering HSV prevalence. The prevalence may vary depending upon geographical location, age, sex, type of test employed, specimen collection and handling procedures as well as clinical history of the patient.

It is recommended that each laboratory determine its own reference range based upon its particular local and population characteristics.

Clinical performance of the ARCHITECT HSV-2 IgG assay was evaluated with samples collected prospectively from 915 individuals from the intended use population. Of the 915 individuals, there were 670 (73%) females and 245 (27%) males. The median age was 35 years (age range: 14 to 99 years). Testing of the specimens was performed at 3 clinical testing sites.

The distribution of ARCHITECT HSV-2 IgG reactive and nonreactive results by age and sex is summarized in the following table.

Table 11. Distribution of HSV-2 IgG reactive and nonreactive results by age and sex.

Age Range (Years)	Sex	n	ARCHITECT HSV-2 IgG Result	
			Number of Reactive (%)	Number of Nonreactive (%)
14 to 20	Female	45	14 (31%)	31 (69%)
	Male	6	1 (17%)	5 (83%)
21 to 30	Female	242	49 (20%)	193 (80%)
	Male	49	11 (22%)	38 (78%)
31 to 40	Female	181	66 (36%)	115 (64%)
	Male	40	10 (25%)	30 (75%)
41 to 50	Female	72	39 (54%)	33 (46%)
	Male	36	12 (33%)	24 (67%)
51 to 60	Female	46	24 (52%)	22 (48%)
	Male	43	16 (37%)	27 (63%)
61 to 70	Female	33	23 (70%)	10 (30%)
	Male	32	16 (50%)	16 (50%)
71 to 99	Female	51	25 (49%)	26 (51%)
	Male	39	10 (26%)	29 (74%)
Total	Female	670	240 (36%)	430 (64%)
	Male	245	76 (31%)	169 (69%)
	Overall	915	316 (35%)	599 (65%)

F Other Supportive Instrument Performance Characteristics Data:

N/A

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.