510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K210793

B Applicant

bioMérieux SA

C Proprietary and Established Names

VIDAS® NEPHROCHECK®

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PIG	Class II	21 CFR 862.1220 - Acute Kidney Injury Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

The test reports an AKIRISK score derived from the measurement of insulin-like growth factor-binding protein (IGFBP-7) and tissue-inhibitor of metalloproteinases 2 (TIMP-2).

C Type of Test:

Quantitative Immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

VIDAS® NEPHROCHECK® is an automated test for use on the VIDAS® 3 instrument for the immunoenzymatic quantitative determination of TIMP-2 (Tissue Inhibitor of Metalloproteinase-2) and IGFBP-7 (Insulin-like Growth Factor-Binding Protein 7) proteins in human urine using the ELFA technique (Enzyme Linked Fluorescent Assay) for calculation of the AKIRISK™ Score.

The VIDAS® NEPHROCHECK® assay is intended to be used in conjunction with clinical evaluation in patients who currently have or have had within the past 24 hours acute cardiovascular and or respiratory compromise and are ICU patients as an aid in the risk assessment for moderate or severe acute kidney injury (AKI) within 12 hours of patient assessment. The VIDAS® NEPHROCHECK® test is intended to be used in patients 21 years of age or older.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The test should not be used as a "standalone test"; test results should be evaluated in the context of all clinical and laboratory data available.
Test results should be used in patients 21 years of age and older.
This test system is for central laboratory use only. It is not for point-of-care use.

D Special Instrument Requirements:

VIDAS 3 Instrument

IV Device/System Characteristics:

A Device Description:

Each VIDAS NEPHROCHECK kit contains 60 tests. The kit is comprised of 60 Reagent Strips, 60 Solid Phase Receptacles (SPR), 1 control, and 1 calibrator (Table 1).

Components of the VIDAS NEPHROCHECK

Kit component		Description
60 Reagent Strips	STR	Ready-to-use.
60 SPR devices 2 X 30	SPR	Ready-to-use. Interior of SPR devices coated with mouse monoclonal IgG anti-lGFBP7 and anti-TIMP-2 + stabilizer of animal origin + preservative.
S1 Calibrator 1 x 1.6 ml (liquid)	C1	Ready-to-use. Buffer containing proteins + stabilizer of animal origin + preservative.
C1 Control 1 x 1.2 ml (liquid)	S1	Ready-to-use. Buffer containing proteins + stabilizer of animal origin + preservative.

The strips consist of 10 wells covered with a labeled foil seal and composed as follows:

Reagent strip components

Well	Reagents
1	Sample well: dispense 100 µL of calibrator, control, or sample.
2	Conjugate: buffer containing alkaline phosphatase-labeled anti-IGFBP-7 monoclonal IgG (mouse) + alkaline phosphatase-labeled anti-TIMP-2 monoclonal IgG (rabbit) + stabilizer of animal origin + preservative.
3	Wash buffer containing preservative
4	Empty well
5	Acid wash buffer
6-7-8	Wash buffer containing preservative.
9	Substrate: 4-Methyl-umbelliferyl phosphate (0.6 mmol/L) + preservative.
10	Reading cuvette with substrate: 4-Methyl-umbelliferyl phosphate (0.6 mmol/L) + preservative.

B Principle of Operation:

The assay principle combines a one-step sandwich enzyme immunoassay method with a final fluorescence detection, also known as enzyme-linked fluorescent assay (ELFA). The sample is transferred into the well containing anti-IGFBP-7 and anti-TIMP-2 antibodies labeled with alkaline phosphatase (conjugate). The sample/conjugate mixture is cycled in and out of the Solid Phase Receptacle (SPR) device several times. This operation enables the two proteins to bind with the immunoglobulins that are fixed to the interior wall of the SPR device and to the conjugate to form a sandwich. Unbound components are eliminated during washing steps. Two detection steps are carried out successively. During each detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR device. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone), the fluorescence of which is measured at 450 nm. For each protein, the intensity of the fluorescence is proportional to the concentration in the sample. At the end of the assay, the protein concentrations are calculated by the VIDAS® 3 instrument in relation to the two calibration curves, one corresponding to each protein, and encoded in the MLE (Master Lot Entry) data. The concentration from each protein, TIMP-2 and IGFBP-7, is converted into a single numerical result called the AKIRISK Score. The VIDAS® NEPHROCHECK® Test result, known as the AKIRISK Score, is automatically calculated by the instrument as the product of the concentrations of the two biomarkers, in ng/mL, divided by 1000, according to the following formula:

$$\text{AKIRISK Score} = (\text{TIMP-2} \times \text{IGFBP-7})/1000$$

V Substantial Equivalence Information:

A Predicate Device Name(s):

NEPHROCHECK Test System

B Predicate 510(k) Number(s):
K171482

C Comparison with Predicate(s):

Device & Predicate Device(s):	K210793	K171482
Device Trade Name	VIDAS® NEPHROCHECK®	NEPHROCHECK Test System
General Device Characteristic Similarities		
Intended Use/Indications for Use	For use in conjunction with clinical evaluation in patients who currently have or have had within the past 24 hours acute cardiovascular and or respiratory compromise and are ICU patients as an aid in the risk assessment for moderate or severe acute kidney injury (AKI) within 12 hours of patient assessment. For use in patients 21 years of age or older.	Same
Intended users	Laboratory healthcare professionals	Same
Specimen	Urine	Same
Sample volume	100 µL	Same
Analyte	TIMP-2 and IGFBP-7	Same
Assay principle	Labeled antibody competition method	Same
Reportable interval for the AKIRISK Score	20-400 ng/mL for IGFBP-7 2-25 ng/ml for TIMP-2 0.04-10.00 for AKIRISK Score	Same
Cutoff	0.3 AKIRISK Score	Same
General Device Characteristic Differences		
Antibody type	Monoclonal antibodies	Polyclonal and monoclonal antibodies
Assay Technique	Enzyme-linked fluorescent assay (ELFA)	Sandwich immunoassay technique. Lateral flow with fluorescent detection.
Automated Instrument	VIDAS 3 instrument	ASTUTE140 Meter

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition
- CLSI EP07-Ed3, Interference Testing in Clinical Chemistry
- CLSI EP09-A3c, Measurement Procedure Comparison and Bias Estimation Using Patient Samples - Third Edition
- CLSI EP12-A2, User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition
- 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

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The device precision was evaluated using a 20-day precision study conducted at 3 clinical laboratories according to CLSI guideline EP05-A3 using 7 pooled native urine samples that included samples below the AKIRISK Score cutoff (Samples S1, S2, and S3), and samples to span the range of the AKIRISK Score (Samples S4, S5, S6, and S7). All samples were tested in duplicate, 2 times per day, for 20 days with a single reagent lot and a single instrument at each site. Each sample was measured 80 times at each site, for a total of 240 measurements per sample. The sponsor assessed Within-Run, Between-Run, Between-Day, and Total Imprecision (Between Site/Instrument/Lot variation).

The sponsor provided information to support the expected imprecision of the individual analytes used in the calculation of the AKIRISK score.

All Sites/Lots (n=240)

Test Specimen	Risk Score Mean	Within-Run		Between Run		Between Day		Total Imprecision (Between-Site/Instrument/Lot)	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
S1	0.05	0.01	18.2	0.00	0.0	0.00	0.0	0.01	22.1
S2	0.05	0.01	10.5	0.00	0.0	0.00	6.7	0.01	16.1
S3	0.19	0.01	5.7	0.01	3.5	0.00	0.0	0.01	7.3
S4	0.71	0.04	5.5	0.02	2.1	0.02	3.4	0.07	10.2
S5	1.73	0.07	3.9	0.05	2.7	0.02	1.1	0.14	7.9
S6	4.28	0.19	4.5	0.07	1.6	0.07	1.5	0.24	5.6
S7	7.48	0.37	4.9	0.00	0.0	0.15	2.0	0.49	6.5

A second study was also performed (8 samples, 2 replicates per run, 2 runs per day, 8 days per lot, 3 lots) that demonstrated that lot-to-lot variation was not a significant contributor to assay imprecision.

Test Specimen	Risk Score Mean	Repeatability (Within-run precision)		Within-lot Precision		Within-laboratory precision (between-lot, within-instrument)	
		SD	%CV	SD	%CV	SD	%CV
S1	0.05	0.00	8.7	0.00	9.7	0.01	12.0
S2	0.06	0.01	15.7	0.01	15.9	0.01	15.9
S3	0.19	0.01	5.9	0.01	7.0	0.01	7.1
S4	0.24	0.02	6.5	0.02	7.7	0.02	8.2
S5	0.73	0.04	6.0	0.05	6.3	0.06	8.0
S6	1.73	0.08	4.4	0.10	5.5	0.15	8.7
S7	4.25	0.18	4.3	0.20	4.7	0.31	7.4
S8	7.46	0.37	5.0	0.40	5.4	0.55	7.4

2. Linearity:

The reportable range of the AKIRISK Score is 0.04 – 10.0. The component measurements of the AKIRISK score (IGFBP-7 and TIMP-2 measurements) were assessed and found to be linear across the reportable range of the AKIRISK Score. However, the AKIRISK Score itself is not expected to be linear.

Low concentration urine was spike with purified recombinant proteins to measure the hook effect at AKIRISK scores approaching 1000. No high dose hook effect was observed for the AKIRISK Score at these values.

3. Analytical Specificity/Interference:

Interference studies were conducted in accordance with CLSI EP07-Ed3 using pooled human urine samples. Interferents were selected from medications, contrast agents, plasma expanders, other urine constituents, isoforms of TIMP and IGFBP, and other biomarkers which have been reported as elevated in the literature in AKI. The sponsor performed testing with substances identified as potentially interfering with IGFBP-7 and TIMP-2. Concentrations were selected based on guidelines in CLSI EP37, expected values for this patient population identified from literature references or concentrations previously tested for similar devices. Two lots of the VIDAS NEPHROCHECK assay were tested using 8 VIDAS 3 instruments. A sample with a high AKIRISK Score, as well as a sample close to the clinical cutoff were used. Interference was defined as any interferents that exhibited greater than ±10% interference in the AKIRISK Score test result.

$$\% \text{ observed interference} = \frac{[\text{Mean Assay Result (Test Pool)} - \text{Mean Assay Result (Control Pool)}]}{\text{Mean Assay Result (Control Pool)}} \times 100$$

If interference was observed at the highest concentration, the effect of the interference was characterized by a dose-response experiment to determine the degree of interference as a function of the interfering substance concentration.

Test substance and highest concentration tested that did not interfere with assay performance

No.	Test Substance	Highest concentration tested with <10% interference (mg/L)
Contrast Agents		
1	Visipaque (Iodixanol)	4,941
2	Omniscan (Gadodaimide)	177
3	Omnipaque (Iohexol)	14,085
4	Magnevist (Gadopentetate Dimeglumine)	422
5	Optiray (Ioversol)	4,944
Plasma Expanders		
6	Dextran 40	22
7	Pentastarch	9
8	Hydroxyethyl starch	6
Drugs and Other Substances		
9	Acetaminophen (Paracetamol)	201
10	Acetone	697
11	Acetylcysteine	1665
12	Acetyl salicylic acid (Aspirin)	652
13	Acyclovir	66
14	Albumin	6,900
15	Albuterol	0.4
16	Amiodarone	42
17	Ammonia	1000
18	Amoxicillin	75
19	Amphotericin	82
20	Ascorbic acid	52.5
21	Atorvastatin	80
22	Bicarbonates	2940
23	Bilirubin conjugated	400
24	Bumetanide	30
25	Caffeine	108
26	Caspofungin	86
27	Cefepime	9
28	Ceftriaxone	840
29	Cephalexin	126
30	Ciprofloxacin	12
31	Clopidogrel	225
32	Dexmedetomidine (Precedex)	0.2
33	Diltiazem (Cardizem)	43
34	Dipyrone	9600
35	Dopamine	1
36	Doripenem	1050
37	Epinephrine	6
38	Ethacryinc acid	19
39	Ethanol	6000
40	Fenoldopam	484

No.	Test Substance	Highest concentration tested with <10% interference (mg/L)
41	Fentanyl	100
42	Fluconazole	75
43	Fluvastatin	80
44	Furosemide	60
45	Gentamicin	30
46	Glucose	9909
47	Human Anti-Mouse Antibodies (HAMA)	2
48	Hemoglobin	60
49	Heparin	21
50	Hydralazine	600
51	Hydrochlorothiazide	6
52	Hydrocodone	0.2
53	Hydrocortisone	720
54	Ibuprofen	500
55	Insulin	0.003
56	Ketorolac	166
57	Lansoprazole	90
58	Linezolid	48
59	Lisinopril	0.3
60	Lorazepam	1
61	Low Molecular Weight Heparin	30
62	Mannitol	18000
63	Metformin	40
64	Methylene blue	3.9
65	Metolazone	60
66	Metoprolol	5
67	Metronidazole	123
68	Midazolam	3.76
69	Morphine	7.8
70	Moxifloxacin	1200
71	Myoglobin	5
72	Nitroglycerin	0.02
73	Norepinephrine	204
74	Omeprazole	8.4
75	Ondansetron	0.342
76	Pancuronium	8
77	Pantoprazole (Protonix)	85
78	Phenobarbital	690
79	Phenylephrine	30
80	Pravastatin	80
81	Prednisone	3
82	Propofol	48
83	Ranitidine	10.5
84	Riboflavin	12
85	Rocuronium	126

No.	Test Substance	Highest concentration tested with <10% interference (mg/L)
86	Salicylic Acid	599
87	Theophylline	60
88	Tobramycin	33
89	Torsemide	12
90	Urobilinogen, synthetic	12
91	Valproic Acid (Valproate)	499
92	Vancomycin	120
93	Vasopressin	5
94	Vecuronium	21
95	Warfarin (Coumadin)	75
Common Urine Constituents		
96	Calcium	600
97	Chloride	5,600
98	Creatinine	1,800
99	Magnesium	240
100	Phosphate	2,800*
101	Potassium	4,000
102	Sodium	3,600
103	Sulfate	4,800
104	Urea	23,000
105	Uric Acid	700
Other Proteins Tested		
106	Cystatin C	3
107	lnterleukin-18 (IL-18)	0.001
108	Kidney Injury Molecule 1 (KIM 1)	0.02
109	Liver Type Fatty Acid Binding Protein (L-FABP)	1
110	N-acetyl-beta-D glucosaminidase (NAG)	0.00004
111	Neutrophil Gelatinase Associated Lipocalin (NGAL)	3
112	Pi-Glutathione-S-transferase (p-GST)	0.1
Potential Cross-Reactive Proteins		
113	Insulin like growth factor- Binding Protein 1 (IGFBP-1)	0.1
114	Insulin like growth factor- Binding Protein 2 (IGFBP.2)	0.25
115	Insulin like growth factor- Binding Protein 3 (IGFBP-3)	1.2
116	Insulin like growth factor- Binding Protein 4 (IGFBP-4)	1.2
117	Insulin like growth factor- Binding Protein 5 (IGFBP-5)	1.2
118	Insulin like growth factor- Binding Protein 6 (IGFBP-6)	1.2
119	Insulin like growth factor 1 (IGF-1)	1.5

No.	Test Substance	Highest concentration tested with <10% interference (mg/L)
120	Insulin like growth factor 2 (IGF-2)	1.5
121	Cysteine-rich motor neuron 1 protein (CRIM1)	1.2
122	Agrin	1.2
123	Serine protease HTRA1 (HTRA1)	1.2
124	Insulin-like growth factor binding protein-like 1 IGFBPL1	1.2
125	Metalloproteinase inhibitor 1 (TIMP-1)	3
126	Metalloproteinase inhibitor 3 (TIMP-3)	2.5
127	Metalloproteinase Inhibitor 4 (TIMP-4)	0.6
128	Matrix Metalloproteinase-2 (MMP-2)	0.03
129	Matrix Metalloproteinase-9 (MMP-9)	0.03

* The sponsor claims no interference from phosphate up to 1,100 mg/L in their labeling despite testing a higher concentration.

Due to the potential of hemoglobin to interfere with results, urine samples with AKIRISK Scores between 0.30 and 0.46 should also be tested with a urine dipstick test for the presence of hematuria. If the blood result is high positive (3+) or the urine sample has some indications of blood in the urine (e.g., pink/red color), the AKIRISK Score may be falsely elevated, and should not be used. Hemoglobin levels above 60 mg/L can lead to a 20% increase in the AKIRISK™ Score.

The effect of pH on AKIRISK Scores around and above the cutoff using samples with AKIRISK Score of 0.3 and 5.0 were evaluated. Pooled human urine samples targeting these AKIRISK Scores were adjusted to target pH values of approximately 4, 6, 8, and 10. There was no significant interference detected at any tested pH level.

4. Assay Reportable Range:

The analytical measuring interval was determined in the linearity and detection limit studies, which support the analytical measuring interval for AKIRISK Score as 0.04 – 10, corresponding to the AKIRISK Score calculation with the two lower limits and the two upper limits of the protein ranges.

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

Metrological Traceability:

The IGFBP-7 and TIMP-2 values obtained with the VIDAS NEPHROCHECK assay were assigned to be traceable to the commercially available predicate device.

Sample Stability:

Sample stability studies were reviewed and found acceptable. Urine samples should be centrifuged within 1 hour of collection. The results support the storage of centrifuged samples for up to 5 hours at 18-25°C in plastic tubes with no additives, or in Low Protein

Binding tubes for up to 5 hours at 18-25°C, 24 hours at 2-8°C, and 6 months at ≤ 60°C (with up to two freeze-thaw cycles).

6. Detection Limit:

Detection limit studies were conducted in accordance with CLSI EP17-A2. Three lots of the assay and 1 instrument were used in the studies. One calibration was performed for each lot of the assay.

1. *Limit of blank (LoB):*
The LoB of each protein was determine using 4 urine samples, tested in duplicate in a single run per day for 8 days, corresponding to 64 values for each of the blank samples.

2. *Limit of detection (LoD) and limit of quantitation (LoQ):*
The LoD and LoQ of IGFBP-7 were determined using 4 individual urine samples obtained from individual healthy donors. The LoD and LoQ of TIMP-2 were determined using 5 individual urine samples obtained from individual healthy donors. Low-level samples were tested in five replicates in a single run per day for 8 days, corresponding to 40 values per sample. The LoD was determined for each lot and each protein consistent with the classical approach described in CLSI EP17-A2. The final LoD for each protein was defined as the maximum LoD value obtained for any of the lots. The final LoD for the VIDAS NEPHROCHECK assay was defined as the AKIRISK Score calculated with the LoD defined for the two proteins by applying the Score formula.

The classical approach described in the CLSI EP17-A2 was used to determine the LoQ. For each lot and each protein the LoQ was defined as 20% total within-lot precision. The final LoQ for each protein was defined as the maximum LoQ value obtained for any of the lots. The final LoQ for the VIDAS NEPHROCHECK assay was defined as the AKIRISK Score calculated with the LoQ defined for the two proteins by applying the Score formula.

The results are presented below.

Detection limits

	AKIRISK Score
LoB	0.002
LoD	0.003
LoQ	0.003

7. Assay Cut-Off:

The assay cut-off is an AKIRISK score of 0.3. This single cut-off value is based on the package insert of the predicate device, as well as the literature, and was validated in the clinical study.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Not applicable. Please refer to section VII.C below.

2. Matrix Comparison:

Not applicable. The assay is intended for use with urine samples only.

C Clinical Studies:

The sponsor conducted a retrospective, multi-center clinical study. Sample sets previously collected in the US from two distinct cohorts were used: A) a sample subset of 400 banked human urine samples from Study A (called Cohort A, or Topaz cohort), and B) a sample set of 126 banked urine samples from Study B (called Cohort B, or Opal cohort). The complete Cohort A and Cohort B were previously evaluated in the predicate's clinical study DEN130031. The subjects in the study were 21 years or older and were ICU patients with respiratory and/or cardiovascular compromise. AKI status for each subject was determined by clinical diagnosis established through independent central adjudication. The Cohort A subset included 69 AKI-positive and 331 non-AKI patients (one of which was excluded due to sample turbidity, resulting in 330 non-AKI patients). The samples available for evaluation were representative of the overall cohort. Cohort B included 29 AKI-positive patients and 97 non-AKI patients. The banked samples were tested at 4 testing sites.

Four lots of the assay were used at each site and 2 calibration cycles per lot were performed.

Comparison of AKIRISK Score > 0.30 and <0.30 to AKI Status for the subset of Cohort A

Subset of Cohort A	AKI status		Total number of VIDAS NEPHROCHECK test results
	AKI	No AKI	
AKIRISK Score > 0.30	62 True Positive	181 False Positive	243
AKIRISK Score < 0.30	7 False Negative	149 True Negative	156
Total number of VIDAS NEPHROCHECK test results	69	330	399

Performance characteristic of the subset of Cohort A

Performance characteristic	Value	95% CI
Sensitivity (TPR)	89.9%	[80.5 - 95.0]%
Specificity (TNR)	45.2%	[39.9 – 50.5]%
NPV	95.5%	[91.0 – 98.2]%
PPV	25.5%	[20.4 – 31.3]%
False Positive Rate (FPR)	54.8%	[49.5 – 60.1]%
False Negative Rate (FNR)	10.1%	[5.0 – 19.5]%

Comparison of AKIRISK Score > 0.30 and <0.30 to AKI Status for Cohort B

Opal Cohort	AKI status		Total number of VIDAS NEPHROCHECK test results
	AKI	No AKI	
AKIRISK Score > 0.30	24 True Positive	58 False Positive	82
AKIRISK Score < 0.30	5 False Negative	39 True Negative	44
Total number of VIDAS NEPHROCHECK test results	29	97	126

Performance characteristic of Cohort B

Performance characteristic	Value	95%CI
Sensitivity (TPR)	82.8%	[65.5 - 92.4]%
Specificity (TNR)	40.2%	[31.0 - 50.2]%
NPV	88.6%	[76.0 - 95.0]%
PPV	29.3%	[20.5 - 39.9]%
FPR (1-Specificity)	59.8%	[49.8 - 69.0]%
FNR (1-Sensitivity)	17.2%	[7.6 - 34.5]%

1. Clinical Sensitivity:

   See above.

2. Clinical Specificity:

   See above.

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

   Not applicable.

D Clinical Cut-Off:

The clinical cutoff is an AKIRISK Score > 0.30. Please refer to section VII.C above.

E Expected Values/Reference Range:

A reference range study was conducted in accordance with CLSI EP28-A3. Banked urine samples from apparently healthy US subjects (378) and US subjects with stable chronic morbidities (372), were tested at 3 sites. Three assay lots were used per site and 2 calibration cycles per lot were performed. The overall reference interval for apparently healthy subjects was <0.04 to 2.50 and for subjects with stable chronic morbidities was <0.04 to 2.66. The reference intervals were comparable for apparently healthy subjects and subjects with stable chronic morbidities, and for males and females from the two cohorts. A breakdown by sex is shown below.

Reference range across different groups

Cohort	Gender	Number of subjects	AKIRISK Score Central 95% Interval
Apparently Healthy Subjects	Female	191	[<0.04 , 2.81]
	Male	187	[<0.04 , 3.06]
	All	378	[<0.04 , 2.50]
Subjects with Stable Chronic Morbidities	Female	191	[<0.04 , 2.91]
	Male	181	[<0.04 , 2.63]
	All	372	[<0.04 , 2.66]

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.