510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K251281

B Applicant

Nova Biomedical Corporation

C Proprietary and Established Names

Nova Max Creat eGFR Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
SHB	Class II	21 CFR 862.1225 - Creatinine Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Creatinine

C Type of Test:

Amperometry; quantitative enzymatic determination of creatinine

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Nova Max Creat eGFR Monitoring System is comprised of the Nova Max Creat eGFR Monitor and the Nova Max eGFR Test Strips.

The Nova Max Creat eGFR Monitoring System is intended for in vitro diagnostic use for the quantitative measurement of creatinine and estimation of glomerular filtration rate (eGFR) in fresh capillary whole blood obtained from the fingertip of adult patients aged 18 and above. The system is intended for single patient home use by prescription only and should not be shared. It is intended for use by patients as an aid to monitor kidney function on the order of a treating healthcare professional.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Nova Max Creat eGFR Monitor

IV Device/System Characteristics:

A Device Description:

The Nova Max Creat eGFR Monitoring System consists of Nova Max Creat eGFR Monitor and Nova Max Creat eGFR Creatinine Test Strips.

Nova Max Creat eGFR Monitor

The hand-held monitor is lightweight, portable, utilizes a 2.8" color touchscreen display and has capability for storage (400 test samples and/or quality control results) and review of data. The monitor is powered by a rechargeable, 3.7 V Li polymer battery.

Nova Max Creat eGFR Creatinine Test Strips

The Nova Max Create eGFR Creatinine Test Strip is a single-use disposable unit. The test strips are packaged into a black desiccant vial (10 test strips per vial). The Nova Max Creat eGFR Creatinine-Test Strip is designed with an electrode that measures creatinine levels. Each test strips contains electrochemical sensors and the following test reagents: creatininase (>0.1 IU), creatinase (>0.015 IU), peroxidase (>0.01IU), sarcosine oxidase (>0.01 IU), mediator (>0.1 µg), and other nonreactive substances.

The Nova Max Creat eGFR Control Solution (Level 1 and Level 2), and the recommended 21 gauge safety lancets (Unistik® 3 Extra, K231124*)* can be purchased separately.

B Principle of Operation:

The monitor and test strip use amperometric biosensor technology for the detection of creatinine in fresh capillary whole blood from fingertips. The blood sample is pulled into the tip of the test strips through capillary action. The test strip contains enzymes that react with creatinine in the sample to produce an electrical current. The monitor measures the current generated that correlates to the creatinine concentration in the blood samples. The test reports a quantitative measurement of the sample creatinine concentration in mg/dL . Furthermore, the monitor calculates eGFR (estimated Glomerular Filtration Rate) using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) 2021 Equation based on the measured creatinine value and user self-reported age (18-120) and sex (male or female). The CKD-EPI 2021 equation for adults is expressed as follows:

$eGFR\ (ml/min/1.73m^2) = 142 \times \min(S_{cr}/k, 1)^{\alpha} \times \max(S_{cr}/k, 1)^{-1.200} \times 0.9938^{Age} \times 1.012$ [if female]

where:
-S_{cr} = serum creatinine in mg/dL
- α = -0.241 (females) or -0.302 (males)
- k=0.7 (females) or 0.9 (males)
-min(S_{cr}/k,1) is the minimum of S_{cr}/k or 1.0
-Age (years)

C Instrument Description Information:

1. Instrument Name:

   Nova Max Creat eGFR Monitor

2. Specimen Identification:

   There is no specimen identification function with this device. Samples are applied directly to the test strip as they are collected.

3. Specimen Sampling and Handling:

   The creatinine test is intended to be used with fresh capillary whole blood from the fingertip. The whole blood is applied directly to the test strip; no handling process is required.

4. Calibration:

   The monitor does not require calibration by the user.

5. Quality Control:

   Two levels of Nova Max Creat eGFR Creatinine Control Solutions (Level 1 and Level 2) are available to use with the test system. Recommendations on when to test the control solutions are provided in the labeling. The Nova Max Creat eGFR Monitor reports quality control tests as Pass or Fail. If a Fail result is displayed, the user is instructed to repeat the quality control

test again using a new test strip. If the second test also fails, the user is instructed to stop testing and to contact customer support for further assistance.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Nova StatSensor Creatinine Hospital Meter System

B Predicate 510(k) Number(s):
K171059

C Comparison with Predicate(s):

Device & Predicate Device(s):	K251281	K171059
Device Trade Name	Nova Max Create eGFR Monitoring System	Nova StatSensor Creatinine Hospital Meter System
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for the quantitative measurement of creatinine	Same
Methodology	Enzyme, Amperometry	Same
Reported results	Creatinine and eGFR	Same
Sample Volume	1.2 µL	Same
General Device Characteristic Differences		
Sample Type	Fingertip capillary whole blood	Capillary, Venous, and Arterial whole blood
Creatinine Measurement Range	0.30-7.00 mg/dL	0.30 – 12.00 mg/dL

VI Standards/Guidance Documents Referenced:

Clinical and Laboratory Standards Institute (CLSI) EP05-A3. Evaluation of Precision of Quantitative Measurement Procedures - Third Edition

CLSI EP06. Evaluation of the Linearity of Quantitative Measurement Procedures – Second Edition

CLSI EP07. Interference Testing in Clinical Chemistry – Third Edition

CLSI EP35. Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures – First Edition

CLSI EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition

CLSI EP37. Supplemental Tables for Interference Testing in Clinical Chemistry – First Edition

CLSI EP25. Evaluation of Stability of In Vitro Medical Laboratory Test Reagents – Second Edition

CLSI EP32-R (Formerly X05-R) Metrological Traceability and Its Implementation; A Report

ISO 17511 Second edition 2020-04. In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples

IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text) Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1

ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021] Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]

IEC 61326-1 Edition 3.0 2020-10 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

IEC 61326-2-6 Edition 3.0 2020-10 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements [Including: Corrigendum 1 (2019)]

IEC 62133-2 Edition1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Day-to-Day Precision

The study was designed following recommendation from CLSI EP05-A3. Day-to-day precision was evaluated using two monitors and 3 lots of test strips. Five levels of controls were tested in duplicate per run in 2 runs per day for 20 days to achieve a minimum of 80 results per samples.

Strip Lot	Control Level	N	Mean (mg/dL)	Total SD	Total CV%
1	Level 1	80	0.56	0.06	11.00%
	Level 2	80	1.33	0.06	4.76%
	Level 3	80	2.58	0.13	5.00%
	Level 4	80	4.13	0.20	4.89%
	Level 5	80	6.03	0.29	4.85%
2	Level 1	80	0.57	0.06	11.16%
	Level 2	80	1.35	0.08	5.66%
	Level 3	80	2.65	0.12	4.64%
	Level 4	80	4.14	0.21	4.98%
	Level 5	80	5.97	0.30	4.99%
3	Level 1	80	0.58	0.06	10.20%
	Level 2	80	1.37	0.08	5.80%
	Level 3	80	2.66	0.13	4.93%
	Level 4	80	4.09	0.20	4.98%
	Level 5	80	6.04	0.29	4.87%

Within Run Precision

Five monitors and three lots of test strips were used in this study. Five lithium heparin venous whole blood specimens spiked with creatinine were prepared to target creatinine concentration of 0.30 – 0.50 mg/dL, 0.60 – 0.90 mg/dL, 1.40 – 1.80 mg/dL, 1.95 – 3.25 mg/dL, and 5.00 – 7.00 mg/dL. Each sample was tested in replicates of eight using each strip lot on each monitor.

Strip Lot	Blood Level (mg/dL)	N	Mean (mg/dL)	SD	CV%
1	Level 1	40	0.47	0.05	10.74%
	Level 2	40	0.82	0.06	6.74%
	Level 3	40	1.68	0.09	5.19%
	Level 4	40	2.81	0.13	4.60%
	Level 5	40	5.83	0.28	4.70%
2	Level 1	40	0.47	0.06	12.17%
	Level 2	40	0.82	0.06	7.31%
	Level 3	40	1.68	0.10	6.17%
	Level 4	40	2.88	0.13	4.40%
	Level 5	40	5.88	0.29	5.00%
3	Level 1	40	0.49	0.06	11.64%
	Level 2	40	0.83	0.06	7.15%
	Level 3	40	1.66	0.10	5.77%
	Level 4	40	2.83	0.14	4.80%
	Level 5	40	5.97	0.29	4.90%

Capillary Fingerstick Precision

A capillary fingerstick precision study was conducted as part of the method comparison study comparing the first and second fingerstick samples between two fingers.
532 subjects performed capillary whole blood testing on two (2) fingers on the candidate device. Precision was assessed for creatinine between the two replicate fingerstick measurements performed by each subject. The mean, SD and the coefficient of variation (CV%) for each subject and grand mean, grand SD and grand CV% across all subjects were calculated. 69 results were removed from the analysis as they were below or above the measuring range of the candidate device.

Range, mg/dL	N	Mean (mg/dL)	Mean SD (mg/dL)	Mean CV%
0.3 – 1.0	75	0.72	0.06	8.5%
1.0 – 1.5	43	1.22	0.08	6.9%
1.5 – 2.0	24	1.76	0.12	6.6%
2.0 – 3.0	67	2.42	0.14	5.9%
3.0 – 4.0	71	3.50	0.20	5.8%
4.0 – 5.0	68	4.50	0.25	5.6%
5.0 – 6.0	70	5.35	0.25	4.8%
6.0 – 7.0	45	6.45	0.24	3.8%

2. Linearity:

Linearity was evaluated using spiked venous whole blood samples with ten different creatinine levels ranging from 0.19 to 8.34 mg/dL. Three test strip lots were used in this study and 10 replicates were run for each concentration level on each strip lot. The results of linear regression for each lot is provided in the table below:

Lot #	Slope	Y-intercept	R^2 value
1	1.0054	0.0137	0.9971
2	1.0020	-0.0027	0.9961
3	0.9855	0.0417	0.9959

The results of the linearity study support the sponsor's claimed measuring range of 0.30 to 7.00 mg/dL. If a sample result is less than 0.30 mg/dL, the result is reported by the monitor as "< 0.30 mg/dL". If a sample result exceeds 7.00 mg/dL, the result is reported by the monitor as ">7.00 mg/dL". "<0.30 mg/dL" and ">7.00 mg/dL" function were validated by the sponsor and were demonstrated to function as intended. If the creatinine result is out of the measuring range, eGFR will not be calculated by the candidate device.

3. Analytical Specificity/Interference:

To assess potential interference, lithium heparin venous whole blood specimens were prepared with target creatinine ranges of 0.5 – 1.5 mg/dL, 2.5 –3.5 mg/dL, and 4.5 – 6.0 mg/dL. Each of these samples was divided into a test pool and a control pool, with the potential interference substances added to the test pool. Each sample was tested using five monitors with two replicates on each of the monitors for a total of 10 replicates for each sample. One lot of test strips was used. The difference between the mean of the test sample (with interferent) and the mean of the control sample (without interferent) was calculated.

For the listed substances at the following concentrations the bias was within ±10% of the control samples for creatinine concentration higher than or equal to 2 mg/dL, and within ±0.14 mg/dL for creatinine concentrations less than 2mg/dL.

Test Substance	Highest concentration tested with no significant interference
Acetaldehyde	0.2 mg/dL
Acetaminophen	15.6 mg/dL
N-Acetyl-L-Cysteine	15 mg/dL
Acetoacetate	20 mg/dL
Ascorbic acid	5.25 mg/dL
Acetylsalicylic Acid	3 mg/dL
Bilirubin (unconjugated)	40 mg/dL
Bilirubin (conjugated)	40 mg/dL
β-Hydroxybutyric Acid	65 mg/dL

Test Substance	Highest concentration tested with no significant interference
Calcium Chloride	20 mg/dL
Chlorpromazine HCl	0.4 mg/dL
Creatine	5 mg/dL
Cholesterol	1000 mg/dL
Dopamine Hydrochloride	2 mg/dL
Ethanol	600 mg/dL
Farxiga (dapagliflozin)	0.6 mg/dL
Formaldehyde	0.4 mg/dL
Glucose	1000 mg/dL
Glycolic Acid	76 mg/dL
Hemoglobin	2600 mg/dL
High Hct and Low Hct	20-70%
Hydroxyurea	4 mg/dL
Intralipid	2000 mg/dL
Ibuprofen	22 mg/dL
Jardiance (empaglifozin)	1.5 mg/dL
Kerendia (finerenone)	1.2 mg/dL
Lactic Acid	108.1 mg/dL
Lithium Heparin	1.2 mg/dL
Lithium Bromide	325.69 mg/dL
Lithium Lactate	90 mg/dL
Lithium Salicylate	3 mg/dL
L-Dopa	0.3 mg/dL
Maltose	360 mg/dL
Methyldopa	5 mg/dL
N-Acetyl-L-Cysteine	15 mg/dL
Paracentamol-4-acetamidopenol	30 mg/dL
pH	8
Potassium bicarbonate	294 mg/dL
Potassium thiocyanate	6 mg/dL
Pyruvate	5 mg/dL
Sodium Thiosulfate	265 mg/dL
Salicylic Acid	60 mg/dL
Semaglutide (Ozempic or Wegovy)	0.144 mg/dL

Test Substance	Highest concentration tested with no significant interference
Triglyceride	1500 mg/dL
Tirzepatide (Mounjaro)	0.9 mg/dL
Urea	120 mg/dL
Uric Acid	23.5 mg/dL

4. Assay Reportable Range:

   0.30 – 7.00 mg/dL

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

   Traceability

   The Nova Max Creat eGFR Monitoring System is traceable to NIST SRM 967b.

   Closed -vial and open-vial test strip stability

   Shelf life (close vial) and open vial stability for the Nova Max Creat eGFR Test Strip was assessed in real-time studies. Study protocol and acceptance criteria were reviewed and found to be acceptable to support the following claims:
   - shelf-life stability until expiration date when stored at 2ºC to 8ºC and 10 to 90% relative humidity (RH)
   - open vial stability for 90 days when stored at 15ºC to 30ºC and 10 to 90% RH

6. Detection Limit:

   The sponsor conducted limit of blank (LoB), limit of detection (LoD) and limit of quantification (LoQ) studies which supported a LoB of 0.078 mg/dL, and a LoD/LoQ of 0.174 mg/dL.

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   See Section VII.3 below for accuracy in the hands of the intended user.

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   See Section VII.3 below for accuracy in the hands of the intended user.

2. Matrix Comparison:

   The device is only intended for use with fresh whole blood from a fingerstick. The sponsor provided additional information to support the use of venous lithium heparin whole blood as a surrogate sample type for some of the analytical and flex studies.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

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

   A lay user study was performed at two clinical sites with a total of 532 participants ranging in age from 23 to 93 using three different test strip lots to assess the accuracy of the Nova Max Creat eGFR Monitoring System in the hands of the lay user. Each subject collected their own capillary fingerstick samples and obtained their creatinine and eGFR results using only system component and instructions provided in the labeling. The creatinine concentrations of the samples ranged from to 0.43 to 6.99 mg/dL. The results from the 46 subjects who had creatinine results above or below the candidate device's measuring range were comparable to the results obtained using the comparator method.

   The creatinine measurement obtained from the 1st fingerstick sample for each subject using the Nova Max Creat eGFR Monitoring System was compared to the corresponding mean of the two venous plasma creatinine measurements measured by laboratory operators using a comparator method. The data was analyzed using Passing-Bablok regression analysis. The fingerstick capillary whole blood eGFR calculations obtained from the 1st fingerstick were also compared to the corresponding calculated eGFR values based on the comparator. 254 capillary whole blood eGFR values below and above the device's eGFR reportable range were excluded from the analysis. The results from the 254 subjects with an eGFR outside of the candidate device's measuring range were comparable to the results obtained using the comparator method.

   Accuracy results for capillary whole blood specimens for creatinine measurement and eGFR calculation are shown in the tables below.

Creatinine

N	Sample range tested as determined by comparator device (mg/dL)	Claimed measuring range (mg/dL)	Slope (95%CI)	Intercept
486	0.43-6.99	0.30-7.00	0.9873 (0.9782, 0.9966)	-0.003947 (-0.05802, -0.02038)

Predicted Creatinine Differences at Specified Medical Decision Levels (MDLs)	
MDL (mg/dL)	Estimated Differences
0.6	-7.9%
1.6	-3.7%
6.0	-1.9%

eGFR

N	Sample range as determined by comparator device (mL/min/1.73m^2)	Claimed range (mL/min/1.73m^2)	Slope (95%CI)	Intercept
228	15 - 90	15-90	1.035 (1.001, 1.068)	-0.02948 (-0.8315, 0.6008)

Predicted eGFR Differences at Specified Medical Decision Levels (MDLs)	
MDL (mL/min/1.37m^2)	Estimated Bias
15	3.3%
30	3.4%
45	3.5%
60	3.5%
90	3.5%

Usability Assessment

The usability of the Nova Max Creat eGFR Monitoring System was assessed by questionnaires given to the study participants following the conclusion of lay user evaluation where the study participants were asked to complete a questionnaire regarding the clarity of the user instructions and the ease of use of the system. From the sponsor's analysis of the questionnaire responses, the participants overall were satisfied with the ease of operation by following the instructions for use.

Readability Evaluation

The readability of the home use labeling was evaluated using a Flesch-Kincaid analysis and demonstrated that the labeling documents met a readability level of grade 8 or lower.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The sponsor provided literature to support the expected values/reference ranges for creatinine and eGFR.

Normal Creatinine Values [1]	
Adult Male	0.7 – 1.3 mg/dL
Adult Female	0.6 – 1.1 mg/dL

Normal eGFR Values [2]	
Age (years)	Average eGFR
20-29	116
30-39	107
40-49	99
50-59	93
60-69	85
75+	75

The labeling also includes the following instructions:

"You should discuss your target creatinine levels with your healthcare provider."

1. Burtis, Carl A. and Bruns, David E., ed. 2015. Tietz Fundamental of Clinical Chemistry, Saunders St. Louis, MO
2. "Estimated Glomerular Filtration Rate (eGFR)." National Kidney Foundation, September 14, 2020. Estimated GFR (eGFR) Test: Kidney Function Levels, Stages, and What to Do Next | National Kidney Foundation

F Other Supportive Instrument Performance Characteristics Data:

1. Altitude Study

   The effect of altitude on the Nova Max Creat eGFR Monitoring System was evaluated by testing 4 spiked venous whole blood samples with concentrations across the device measuring range (level 1: 0.5 – 1.5 mg/dL, level 2: 1.5 – 3.0 mg/dL, level 3: 3.0 – 4.5 mg/dL and level 4: 4.5 – 7.0 mg/dL) at sea level and at 12,119 ft above sea levels using three lots of test strips and three monitors. The results obtained with the candidate device at 12,119 ft above sea level was compared to the results obtained with the candidate device at sea level.

The results of the study demonstrate that the system yields accurate results up to altitudes of 12,119 feet above sea level.

2. Operation Conditions Study

   The sponsor performed operation condition studies to evaluate the operating temperature and relative humidity (RH) ranges for the Nova Max Creat eGFR system. Venous whole blood samples were adjusted to three creatinine concentration levels (0.97, 2.67 and 5.44 mg/dL) and tested under four extreme temperature and humidity combinations (low temperature/low humidity 15ºC/10% RH, low temperature/high humidity15ºC/90%RH, high temperature/low humidity 40ºC/10% RH, and high temperature/high humidity 40ºC/90% RH). The results obtained were compared to those obtained using the candidate device at a nominal condition (25ºC/50%RH). The results support the claimed operating conditions for the system of 59°F~104°F (15°C~40°C) and 10%~90% relative humidity.

3. Sample Volume (Detection) Study

   The sponsor conducted a sample volume study using venous blood samples prepared at three creatinine levels (0.92, 2.33 and 5.21 mg/dL) that were tested at different sample volumes (0.9, 1.0, 1.1, and 1.2 µL). The results support the claimed sample volume of 1.2 µL and demonstrate that the insufficient sample volume error feature functions as intended with sample volumes less than 1.2 µL.

4. Flex Studies

   The following additional flex studies were performed with the Nova Max Creat eGFR system: moving the monitor during measurement, atypical monitor position, monitor drop test, altered (cut, bent, scratched, wet, dried) test strips, flicking the test strips, double dosing the test strips, test strip early removal, delay in sample testing, testing with incorrect test strips, testing with previously used test strips, sample testing with $1^{st}/2^{nd}/3^{rd}$ blood drop, and a variety of durability testing (QC solution (closed vial) stored at room temperature, QC solution stored with a cap off, test strip (open vial) stored at extreme temperature and humidity conditions). The results demonstrated that the performance of the Nova Max Creat eGFR system is robust under these conditions.

5. Infection Control Testing and Robustness Testing

   The system is intended for single-patient use only. Disinfection efficacy studies were performed with the external meter materials by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) following the recommended cleaning and disinfection procedures with the following disinfectants: Clorox Healthcare ®Bleach Germicidal Wipes (EPA# 67619-12) and Super Sani-Cloth®Germicidal Disposable Wipe (EPT # 9480-4). A robustness study was also conducted by the sponsor demonstrating that there was no change in performance nor in the external materials of the meter after 1095 cleaning and disinfection cycles using Clorox Healthcare ®Bleach Germicidal Wipes (EPA# 67619-12) and Super Sani-Cloth®Germicidal Disposable Wipes (EPT # 9480-4). The robustness studies were adequate to support 5 years of single-patient device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. EMC and Electrical Safety

   The sponsor provided documentation certifying that acceptable safety and EMC testing had been performed. The Nova Max Creat eGFR system was found to be compliant.

7. Software documentation was reviewed and found to be acceptable.

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.