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

A. 510(k) Number:

k170463

B. Purpose for Submission:

New device

C. Measurand:

β-Ketone, as beta-hydroxybutyrate, in fingertip capillary whole blood and venous EDTA whole blood

D. Type of Test:

Quantitative amperometry, β-Ketone (beta-hydroxybutyrate)

E. Applicant:

i-SENS, Inc.

F. Proprietary and Established Names:

KetoSens Blood β-Ketone Monitoring System
KetoSens Multi Blood β-Ketone Monitoring System

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.1435, Ketones (nonquantitative) test system

2. Classification:

   Class I, meets limitations of exemptions 21 CFR §862.9(c)(5)

3. Product codes:

   JIN, Nitroprusside, Ketones (urinary, non-quant.)

4. Panel:

   Clinical Chemistry, 75

H. Intended Use:

1. Intended use(s):

   See indication(s) for use below.

2. Indication(s) for use:

   KetoSens Blood β-Ketone Monitoring System is intended to be used for the quantitative measurement of β-Ketone (beta-hydroxybutyrate) level in capillary whole blood samples drawn from the fingertip. The KetoSens Blood β-Ketone Monitoring Systems are for self-testing outside the body (for in vitro diagnostic use) in the home as an aid to monitor the effectiveness of diabetes control program. The system is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. This system is intended to be used by a single person and should not be shared.

   The KetoSens Blood β-Ketone Test Strips work with the KetoSens Blood β-Ketone Meter to quantitatively measure Blood β-Ketone in capillary whole blood samples drawn from the fingertip.

   KetoSens Multi Blood β-Ketone Monitoring System is intended to be used for the quantitative measurement of β-Ketone (beta-hydroxybutyrate) level in capillary whole blood from the fingertip and venous EDTA whole blood. KetoSens Multi Blood β-Ketone Monitoring System is intended for in vitro diagnostic use and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. The system is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. This system should only be used with single-use, auto-disabling lancing devices.

   The KetoSens Multi Blood β-Ketone Test Strips work with the KetoSens Multi Blood β-Ketone Meter to quantitatively measure Blood β-Ketone in capillary whole blood samples drawn from the fingertip and venous whole blood drawn in professional healthcare settings.

3. Special conditions for use statement(s):

   For the KetoSens Blood β-Ketone Monitoring System:

   - The system should not be used to test neonates.
   - Do not test samples other than fresh capillary whole blood obtained from the fingertip.

- Do not use the system at altitudes above 10,000 feet (3000 meters).
- Do not use when Hematocrit is outside the acceptable hematocrit range for testing of 20% to 55%.
- Severe dehydration (excessive water loss) may cause inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- For in vitro diagnostic use only.
- Critically ill patients should not be tested with this device.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Incorrect result may occur in individuals who are dehydrated.
- The meter and lancing device are for single patient use. Do not share these items with anyone, including other family members! Do not use on multiple patients!
- Do not reuse; each test strip is for single use only.
- Do not use when humidity is higher than 90% and lower than 10%, as extremes in humidity may affect results.
- For single patient use only.
- For over-the counter use
- The system is not intended for use in the diagnosis of or screening for diabetes mellitus.

For the KetoSens Multi Blood β-Ketone Monitoring System:

- For prescription use only
- The system should not be used to test neonates.
- Do not test samples other than fresh capillary whole blood obtained from the fingertip or venous EDTA whole blood.
- Do not use at altitudes above 10,000 feet (3000 meters).
- Do not use when Hematocrit is outside the acceptable hematocrit range for testing of 20% to 55%.
- Severe dehydration (excessive water loss) may cause inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- For in vitro diagnostic use only.
- Critically ill patients should not be tested with this device.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Incorrect result may occur in individuals who are dehydrated.
- Do not reuse; each test strip is for single use only.
- This system should only be used with single-use, auto-disabling lancing devices.
- Do not use when humidity is higher than 90% and lower than 10%, as extremes in humidity may affect results.
- The system is not intended for use in the diagnosis of or screening for diabetes mellitus

4. Special instrument requirements:

   KetoSens Blood β-Ketone Meter
   KetoSens Multi Blood β-Ketone Meter

I. Device Description:

The KetoSens Blood β-Ketone Monitoring System consists of the KetoSens Blood β-Ketone Meter, KetoSens Blood β-Ketone Test Strips, KetoSens β-Ketone Control Solutions (Level A and B), Lancing device, Lancets, Carrying Case, Owner's Booklet, Quick Reference Guide, and two lithium batteries. The system is for self-testing. The KetoSens Blood β-Ketone Test Strips and KetoSens β-Ketone Control Solutions (Level A and B) are purchased separately.

The KetoSens Multi Blood β-Ketone Monitoring System consists of the KetoSens Multi Blood β-Ketone Meter, KetoSens Multi Blood β-Ketone Test Strips, KetoSens β-Ketone Control Solutions (Level A and B), Owner's Booklet, two lithium batteries, and Carrying Case. The system is for multiple-patient testing. The KetoSens Blood β-Ketone Test Strips and KetoSens β-Ketone Control Solutions (Level A and B) are purchased separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Nova Max Plus Blood Glucose and β-Ketone Monitoring System

2. Predicate 510(k) number(s):

   k091547

3. Comparison with predicate:

Similarities and differences		
Item	Candidate device KetoSens Blood β-Ketone Monitoring System k170463	Predicate device Nova Max Plus Blood Glucose and β-Ketone Monitoring System k091547
Intended use	For the quantitative measurement of β-Ketone in whole blood as an aid to monitor the effectiveness of diabetes control program.	Same
Use type	Single-patient patient use	For Over-the-Counter use
Specimen	Capillary whole blood from the fingertip, and venous EDTA whole	Capillary whole blood from fingertip

Similarities and differences		
Item	Candidate device KetoSens Blood β-Ketone Monitoring System k170463	Predicate device Nova Max Plus Blood Glucose and β-Ketone Monitoring System k091547
	blood	
Method	Amperometric	Same
Test strip active reagent	β-hydroxybutyrate dehydrogenase	Same
Analytical measurement range	0.1 - 8.0 mmol/L	Same
Sample volume	0.5 µL	0.8 µL
Hematocrit range	20% - 55%	25% - 60%
Operating temperature	50°F - 100°F	Same
Operating humidity	10% - 90% RH	Same
Test Strip Calibration Coding	Auto-coding, no user input of calibration code required	Same

Similarities and differences		
Item	Candidate device KetoSens Multi Blood β-Ketone Monitoring System k170463	Predicate device Nova Max Plus Blood Glucose and β-Ketone Monitoring System k091547
Intended use	For the quantitative measurement of β-Ketone in whole blood as an aid to monitor the effectiveness of diabetes control program.	Same
Use type	Multiple patient use	For Over-the-Counter use
Specimen	Capillary whole blood from the fingertip, and venous EDTA whole blood	Capillary whole blood from fingertip
Method	Amperometric	Same
Test strip active reagent	β-hydroxybutyrate dehydrogenase	Same
Analytical measurement range	0.1 - 8.0 mmol/L	Same
Sample volume	0.5 µL	0.8 µL

Similarities and differences		
Item	Candidate device KetoSens Multi Blood β-Ketone Monitoring System k170463	Predicate device Nova Max Plus Blood Glucose and β-Ketone Monitoring System k091547
Hematocrit range	20% - 55%	25% - 60%
Operating temperature	50°F - 100°F	Same
Operating humidity	10% - 90% RH	Same
Test Strip Calibration Coding	Auto-coding, no user input of calibration code required	Same

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline.

CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.

CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline.

CLSI EP25-A Evaluation of Stability of In Vitro diagnostic reagents; approved guideline.

L. Test Principle:

The test principle of the KetoSens Blood β-Ketone Monitoring System/KetoSens Multi Blood β-Ketone Monitoring System is based on the amperometric detection of beta-hydroxybutyrate (also known as 3-hydroxybutyrate) in whole blood. β-hydroxybutyrate is converted by the enzyme β-hydroxybutyrate dehydrogenase to acetoacetate. The magnitude of electrical current resulting from this enzymatic reaction is proportional to the amount of β-hydroxybutyrate present in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

The only differences between the KetoSens Blood β-Ketone Monitoring System and KetoSens Multi Blood β-Ketone Monitoring System are the trade name and intended use (single-patient home use vs. multiple-patient use); therefore, performance testing conducted on the KetoSens Blood β-Ketone Monitoring System.

a. *Precision/Reproducibility:*

Repeatability:
Venous EDTA whole blood was spiked with five different β-hydroxybutyrate concentrations (0.4, 1.1, 3.4, 5.2, and 6.9 mmol/L) and tested on ten KetoSens Blood β-Ketone meters. Ten replicates were tested per meter per concentration with each of three lots of test strips. The results are summarized below:

Concentration (mmol/L)	N	Mean (mmol/L)	SD (mmol/L)	%CV
0.4	300	0.39	0.027	6.8
1.1	300	1.08	0.056	5.1
3.4	300	3.38	0.126	3.7
5.2	300	5.16	0.182	3.5
6.9	300	6.91	0.248	3.6

Intermediate Precision:
Intermediate precision was evaluated by 10 operators using three lots of test strips. Each operator was provided with three KetoSens Blood β-Ketone meters. Each meter was assigned to a test strip lot. Each operator conducted testing of three different test strip lots a day for 20 days using three β-Ketone control solutions. The results are summarized below:

Control Level	N	Mean (mmol/L)	SD (mmol/L)	%CV
Level 1	600	0.63	0.049	7.7
Level 2	600	2.23	0.085	3.8
Level 3	600	4.04	0.173	4.3

b. *Linearity/assay reportable range:*

The linearity of KetoSens Blood β-Ketone Monitoring System was evaluated using venous EDTA whole blood spiked with β-hydroxybutyrate. Nine whole blood samples were adjusted to the following β-hydroxybutyrate concentrations: 0.1, 0.3, 0.7, 1.2, 2.1, 3.9, 5.7, 7.7, and 9.3 mmol/L. The concentrations were assigned using the Randox RANBUT d-3-Hydroxybutyrate assay on the RX imola analyzer. The summary of the linear regression analysis for each lot was as follow:

Lot 1: $y = 1.0034x - 0.0145$; $R^2 = 0.999$
Lot 2: $y = 1.0250x - 0.0466$; $R^2 = 0.998$
Lot 3: $y = 1.0209x - 0.0323$; $R^2 = 0.998$

The results of the study support the sponsor's claimed β-Ketone measurement range

of 0.1 to 8.0 mmol/L for both systems.

Validation testing was performed demonstrating that the meter displays 'HI' when the measurement result is greater than 8.0 mmol/L and 'LO' when the measurement result is less than 0.1 mmol/L.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability:
The KetoSens Blood β-Ketone Monitoring System and KetoSens Multi Blood β-Ketone Monitoring System are traceable to an in-house standard prepared from commercially available control materials. The method comparison study was performed using the Randox RANBUT d-3-Hydroxybutyrate assay on the RX imola analyzer as the comparator method (see Section M.2.a.).

Test strip stability:
The KetoSens Blood β-Ketone Test Strips are provided in individual foil packages. The shelf life stability of the foil packaged test strips was assessed in real-time studies. The study protocol and acceptance criteria were reviewed and found acceptable to support the sponsor's claimed stability of 15 months when stored under the recommended storage conditions of 39°F to 86°F (4 to 30°C) and relative humidity of 20 to 80%.

Because each test strip is individually packaged, open vial stability testing is not necessary.

d. *Detection limit:*

The β-Ketone measuring range is 0.1 to 8.0 mmol/L. The range is validated under the linearity study. See section M.1.b.

e. *Analytical specificity:*

Interference testing was performed to evaluate exogenous and endogenous substances using venous EDTA whole blood spiked at two β-hydroxybutyrate concentrations of 0.6 and 2.8 mmol/L. The samples were divided into two aliquots: control (with no added interferent) and test (with added interferent at a toxic level or 10 times the known therapeutic level). Each sample was measured using 20 KetoSens Blood β-Ketone meters and three test strip lots.

The sponsor defined no significant interference according to the following:

The following table lists the concentration of each substance at which no significant interference was detected. At the β-hydroxybutyrate concentration of 0.6 mmol/L the %bias ranged from -17% to 12%. At the β-hydroxybutyrate concentration of 2.8 mmol/L the % bias ranged from -8.3% to 4.3%. The following table lists the high concentrations at which no significant interference was observed:

Substance	Highest concentration tested at which no significant interference is observed (mg/dL)
Acetaminophen	20
Ascorbic acid	3
Bilirubin,	20
Cholesterol	500
Creatinine	30
Dopamine	13
EDTA	200
Galactose	60
Gentisic acid	50
Hemoglobin	500
Heparin, U/dL	8000
Ibuprofen	40
L-Dopa	5
Maltose	1000
Methyldopa	10
Salicylate	60
Tolazamide	100
Tolbutamide	100
Triglycerides	3000
Uric acid	20
Xylose	25
Reduced Glutathione	20
Catopril	10
Tetracycline	30
Glucose	360
Acetone	60
Acetoacetate	10

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Point of Care study:
To assess the performance of the KetoSens Multi Blood β-Ketone Monitoring System in the hands of the intended operators, a point of care (POC) study was conducted by

six health care professionals at three POC sites.

The POC study was performed on 136 patients from the intended use population using six KetoSens Multi Blood β-Ketone meters and three lots of KetoSens Multi Blood β-Ketone test strips. Capillary blood was collected from each patient and analyzed once using the KetoSens Multi Blood β-Ketone Monitoring System. Venous blood was collected from the same patient using an EDTA collection tube and analyzed once using the KetoSens Multi Blood β-Ketone Monitoring System. The β-Ketone measurements on the fingertip capillary whole blood and venous EDTA whole blood were compared to those obtained using the Randox RANBUT d-3-Hydroxybutyrate assay on the RX imola analyzer. To test specimens with β-Ketone concentrations at the high end of the claimed measuring range, 12 of 136 of these were altered by spiking analyte into both capillary and venous whole blood samples. The results are summarized below:

Fingertip capillary whole blood:

β-Ketone concentration <1.5 mmol/L

Within ± 0.15 mmol/L	Within ± 0.225 mmol/L	Within ± 0.30 mmol/L
115/124 (92.7%)	121/124 (97.6%)	124/124 (100%)

β-Ketone concentration ≥1.5 mmol/L

Within ±5%	Within ±10%	Within ±15%	Within ±20%
2/12 (16.7%)	8/12 (66.7%)	11/12 (91.7%)	12/12 (100%)

Venous EDTA whole blood:

β-Ketone concentration <1.5 mmol/L

Within ± 0.15 mmol/L	Within ± 0.225 mmol/L	Within ± 0.30 mmol/L
113/123 (91.9%)	118/123 (95.9%)	121/123 (98.4%)

β-Ketone concentration ≥1.5 mmol/L

Within ±5%	Within ±10%	Within ±15%	Within ±20%
7/13 (53.8%)	12/13 (92.3%)	13/13 (100%)	13/13 (100%)

The method accuracy was further analyzed by Passing-Boblok regression analysis. The results are given below.

Fingertip capillary whole blood:

Site	n	Range	Slope	Intercept	R^2
1	47	0.1 – 7.9	1.076	-0.004	0.998
2	45	0.1 – 7.8	1.107	-0.024	0.989
3	44	0.1 – 7.5	0.947	0.001	0.998
All sites combined	136	0.1 – 7.9	1.050	-0.006	0.995

Venous EDTA whole blood:

Site	n	Range	Slope	Intercept	R^2
1	47	0.1 – 7.7	1.089	-0.004	0.999
2	45	0.1 – 7.0	1.090	-0.026	0.996
3	44	0.1 – 7.9	1.064	-0.005	0.998
All sites combined	136	0.1 – 7.9	1.087	-0.010	0.998

The usability of the system was assessed by a questionnaire given to the operators of the system following the conclusion of the study. The sponsor's analysis of the responses to the questionnaire found the comprehension level of KetoSens Multi Blood β-Ketone Monitoring System user manual was high and no operator thought the use of the system difficult.

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Lay user study for OTC use:
To assess the performance of the KetoSens Blood β-Ketone Monitoring System in the hands of the intended users, a lay user study was conducted with 185 lay user participants using three KetoSens Blood β-Ketone meters and three lots of KetoSens Blood β-Ketone test strips. Each lay user participants self-tested their fingertip capillary blood β-Ketone level unassisted, and was given only the instructions and training materials routinely provided with the system.

The lay user β-Ketone measurements were compared to those obtained by trained users using the Randox RANBUT d-3-Hydroxybutyrate assay on the RX imola analyzer. The range of β-Ketone concentrations across all subjects was 0.017 to 1.054 mmol/L (based on comparator method). Each sample was measured in singlicate. The results are summarized below:

β-Ketone concentration <1.5 mmol/L

Within ± 0.15 mmol/L	Within ± 0.225 mmol/L	Within ± 0.30 mmol/L
183/185 (98.9%)	185/185 (100%)	185/185 (100%)

The method accuracy was further analyzed by Passing-Boblok regression analysis. The results are given below.

$y=0.994x - 0.007$, $R^2= 0.970$

Readability Evaluation: The readability of the home use labeling was evaluated using a Flesch-Kincaid analysis and demonstrated that the grade level scores were less than 8th grade.

4. Clinical cut-off**:**

Not applicable.

5. Expected values/Reference range:

Normal levels of β-Ketone are <0.6 mmol/L. β-Ketone levels of 0.6–1.5 mmol/L are moderately elevated, 1.5–3.0 mmol/L indicates risk of ketoacidosis, and >3.0 mmol/L is usually accompanied by acidosis. From *A. Rewers, Current Controversies in Treatment and Prevention of Diabetic Ketoacidosis, Advances in Pediatrics 57 (2010) 247–267.*

N. Instrument Name:

KetoSens Blood β-Ketone Meter
KetoSens Multi Blood β-Ketone Meter

O. System Descriptions:

1. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes ___X_____ or No _____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes ___X_____ or No _____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ____X____ or No _____

3. Specimen Identification:

   There is no sample identification function with this device.

4. Specimen Sampling and Handling:

   The KetoSens Blood β-Ketone Monitoring System is intended to be used with capillary whole blood from the fingertip or venous whole blood. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   There is no calibration required for the KetoSens Blood β-Ketone Monitoring System by the user.

6. Quality Control:

   Two levels of KetoSens β-Ketone Control Solution are available and must be purchased separately. The kit box label states that controls are necessary but not included and must be purchased separately.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. Hematocrit Study:
   The effect of varying hematocrit level on the measurement of β-Ketone concentration was evaluated using venous EDTA whole blood samples with hematocrit levels of 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, and 60%. Five different β-hydroxybutyrate concentrations of 0.5, 1.6, 2.9, 4.2, and 6.1 mmol/L were prepared at each of the five different hematocrit levels. The β-Ketone concentration was measured using 30 meters and three lots of test strips. The % bias at each hematocrit level relative to a plasma sample of the same concentration run on the Randox RANBUT d-3-Hydroxybutyrate assay on the RX imola analyzer was calculated. The results support the claimed acceptable hematocrit range of 20 to 55%.

2. Altitude study:
   An altitude/oxygen dependency study was performed to assess the effect of low oxygen levels when the system is used at elevations above sea level. For testing, three different altitudes (0, 5000, and 10000 feet) were simulated. Venous whole blood was spiked to achieve three β-hydroxybutyrate concentrations (0.6, 2.4, and 4.9 mmol/L) as measured by the Randox RANBUT d-3-Hydroxybutyrate assay on the RX imola analyzer. Each sample was tested across three lots of test strips using 15 meters. The results demonstrated acceptable bias to support the claim that altitudes up to 10,000 feet have no significant effect on β-Ketone measurement with the KetoSens Blood β-Ketone Monitoring System.

3. Temperature and Humidity Study:
   The sponsor performed operating condition studies to evaluate the operating temperature and relative humidity (RH) ranges. Venous whole blood samples at three β-hydroxybutyrate concentrations (0.5, 2.5, and 5.0 mmol/L) were evaluated using the KetoSens Blood β-Ketone Monitoring System. Each sample was tested at the temperature and humidity conditions shown below using 30 meters and three lots of ketone test strips for a total of 30 replicates per temperature/humidity condition. The results were compared with those obtained using the Randox RANBUT d-3-Hydroxybutyrate assay on the RX imola analyzer was calculated.

   50°F (10°C) and 10% RH, 40% RH, 90% RH
   59°F (15°C) and 10% RH, 40% RH, 90% RH
   73°F (23°C) and 10% RH, 40% RH, 90% RH
   86°F (30°C) and 10% RH, 40% RH, 90% RH
   104°F (40°C) and 10% RH, 40% RH, 90% RH

   The results support the sponsor's claimed operating temperature range of 50°F to 104°F and operating relative humidity range of 10 to 90%.

4. Sample Volume Study:
   A sample volume study was conducted to verify the minimum sample volume required for the KetoSens Blood β-Ketone Monitoring System. Three venous whole blood samples were spiked to β-hydroxybutyrate concentrations of 0.7, 2.4, and 4.4 mmol/L, as measured by the Randox RANBUT d-3-Hydroxybutyrate assay on the RX imola analyzer, to evaluate the effect of different sample volumes (0.4, 0.5, 0.6, and 1.0 µL) on the accuracy performance of the device and validation of error message when sample volume is too low. Three lots of test strips and 5 meters were used. Results from the study support the claimed minimum sample volume of 0.5 µL and that the insufficient volume error message (Er4) functioned as intended.

5. Infection Control Studies:
   The KetoSens Blood β-Ketone Monitoring System is intended for single-patient use, and the KetoSens Multi Blood β-Ketone Monitoring System is intended for multiple-patient use. Disinfection efficacy studies were performed on the materials comprising the meters by an outside commercial laboratory service to demonstrate complete inactivation of

hepatitis B virus (HBV) with Clorox Healthcare Bleach Germicidal Wipes (EPA Reg. No. 67619-12). Robustness studies were performed by the sponsor demonstrating that there were no changes in performance or to the external materials of the meters after 10,950 cleaning and 10,950 disinfection cycles with Clorox Healthcare Bleach Germicidal Wipes. The robustness studies were designed to simulate 5 years of single-patient use and 3 years of multiple-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. Electromagnetic Compatibility:
   The sponsor provided documentation certifying that acceptable electromagnetic testing had been performed and the KetoSens Blood β-Ketone Monitoring System was found compliant.

7. Customer service is available Monday through Saturday 9:00 am to 9:00 pm EST by calling 1-800-429-5001.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.