510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K241165

B Applicant

Siemens Healthcare Diagnostics Inc.

C Proprietary and Established Names

Atellica® IM High-Sensitivity Troponin I (TnIH)

D Regulatory Information

Product Code	Classification	Regulation Section	Panel
MMI	Class II	21 CFR 862.1215 - Creatine Phosphokinase/Creatine Kinase Or Isoenzymes Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Modification to the indications for use for the Atellica IM High-Sensitivity Troponin I (TnIH) assay cleared in K171566.

B Measurand:

Cardiac troponin I (cTnI)

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:
The Atellica® IM High-Sensitivity Troponin I (TnIH) assay is for in vitro diagnostic use in the quantitative measurement of cardiac troponin I in human serum or plasma (lithium heparin) using the Atellica® IM Analyzer. The assay can be used to aid in the diagnosis of acute myocardial infarction (AMI).

The Atellica IM TnIH assay can be used as an aid in prognosis for 30-, 90-, 182-, and 365-day all-cause mortality (ACM) and major adverse cardiac events (MACE) in patients presenting with signs and symptoms suggestive of acute coronary syndrome (ACS). MACE consists of myocardial infarction, urgent revascularization, cardiac death, or heart failure hospitalization.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

For *in vitro* diagnostic use

D Special Instrument Requirements:

Atellica IM Analyzer

IV Device/System Characteristics:

A Device Description:

The Atellica IM High-Sensitivity Troponin I (TnIH) assay was described in K171566.

B Principle of Operation:

The principle of operation for the Atellica IM High-Sensitivity Troponin I (TnIH) assay was described in K171566.

V Substantial Equivalence Information:

A Predicate Device Name(s):
VITROS Immunodiagnostic Products Troponin I ES Reagent Pack

B Predicate 510(k) Number(s):
K062838

C Comparison with Predicate(s):

Device & Predicate Device(s):	Candidate Device K241165	Predicate Device K062838
Device Trade Name	Atellica® IM High-Sensitivity Troponin I (TnIH)	VITROS Immunodiagnostic Products Troponin I ES Reagent Pack
General Device Characteristic Similarities		
Intended Use/Indications For Use	The assay can be used to aid in the diagnosis of acute myocardial infarction (AMI).	Same
Detection Technology	Chemiluminescence	Same
Type of Immunoassay	Sandwich Immunoassay	Same
Analyte	Cardiac Troponin I	Same
General Device Characteristic Differences		
Intended Use/Indications For Use	The assay can be used as an aid in prognosis for 30-, 90-, 182-, and 365-day all-cause mortality (ACM) and major adverse cardiac events (MACE) in patients presenting with signs and symptoms suggestive of acute coronary syndrome (ACS). MACE consists of myocardial infarction, urgent revascularization, cardiac death, or heart failure hospitalization	For the quantitative measurement of cardiac Troponin I (cTnI) in human serum and plasma (heparin and EDTA) using the VITROS Immunodiagnostic System, to aid in the assessment of myocardial damage and risk stratification. Aids in the risk stratification of patients with non-ST-segment elevation acute coronary syndromes with respect to relative risk of mortality, myocardial infarction (MI) or increased probability of ischemic events requiring urgent revascularization procedures.
Specimen Type	Serum and lithium heparin plasma	Serum, lithium heparin plasma, and EDTA plasma
Measuring Range	2.50–25,000.00 pg/mL	12-80,000 pg/mL
Upper 99th Percentile Cutoff	Lithium Heparin: Female: 34.11 pg/mL Male: 53.48 pg/mL	34 pg/mL AMI Diagnostic Cutoff 120 pg/mL

Device & Predicate Device(s):	Candidate Device K241165	Predicate Device K062838
	Combined: 45.20 pg/mL Serum: Female: 38.64 pg/mL Male: 53.53 pg/mL Combined: 45.43 pg/mL Overall: 45.20 pg/mL	
Calibration	2-point calibration	3 levels

VI Standards/Guidance Documents Referenced:

Not Applicable

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   The precision of the Atellica IM High-Sensitivity Troponin I (TnIH) assay was established in K171566.

2. Linearity:

   The linearity of the Atellica IM High-Sensitivity Troponin I (TnIH) assay was established in K171566.

3. Analytical Specificity/Interference:

   The analytical specificity/interference of the Atellica IM High-Sensitivity Troponin I (TnIH) assay was established in K171566.

4. Assay Reportable Range:

   The reportable range of the Atellica IM High-Sensitivity Troponin I (TnIH) assay was established in K171566.

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

   The traceability, sample stability, and expected values of the Atellica IM High-Sensitivity Troponin I (TnIH) assay are unchanged since K171566.

6. Detection Limit:

   The detection limit of the Atellica IM High-Sensitivity Troponin I (TnIH) assay was established in K171566.

7. Assay Cut-Off:

   The assay cut-off of the Atellica IM High-Sensitivity Troponin I (TnIH) assay was established in K171566.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable.

2. Matrix Comparison:

   Not applicable. All performance studies in K171566 were performed in all applicable matrices (lithium heparin plasma and serum).

C Clinical Studies:

1. Clinical Sensitivity:

   The clinical sensitivity of the Atellica IM High-Sensitivity Troponin I (TnIH) assay as an aid in the diagnosis of AMI was established in K171566.

2. Clinical Specificity:

   The clinical specificity of the Atellica IM High-Sensitivity Troponin I (TnIH) assay as an aid in the diagnosis of AMI was established in K171566.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):
   A clinical study was performed to evaluate the prognostic performance of the device using the same clinical cohort described in K171566. Patients presenting to the emergency department with signs and symptoms suggestive of ACS were followed up for 30-, 90-, 182-, and 365-day progression to ACM and MACE (consisting of myocardial infarction, urgent revascularization, cardiac death, or heart failure hospitalization). At each time point, the risk (cumulative incidence) and hazard ratios were calculated for populations with baseline cardiac troponin I levels ≤ or > the overall 99th percentile value. Lithium heparin plasma and serum specimens were collected and baseline cardiac troponin I levels were established using the Atellica IM Analyzer testing the first blood draw for each subject presenting to the emergency department. The median time of the first blood draw was 93 minutes after presentation to the emergency department.

Kaplan-Meier curves were generated to display the absolute risk (cumulative incidence) of ACM and MACE outcomes. Analyses were performed separately for both serum and lithium heparin plasma sample types using the overall 99th percentile value. Tables for pre- and post-test risk and unadjusted hazard ratios, adjusted hazard ratios (adjusted for prior revascularization, prior heart failure, estimated glomerular filtration rate (eGFR), hypertension and sex), multivariable Cox proportional hazards (PH) model parameters, and event types, as well as Kaplan-Meier curves, are presented for the following populations based on the overall 99th percentile value. Smoking, diabetes, Body Mass Index (BMI), race, and age were also evaluated and were not significantly associated with cumulative ACM/MACE for any cohort in this clinical population. Prior MI, statins, and depressed left ventricular ejection fraction (LVEF) were evaluated and removed from the model due to multicollinearity. The cohorts and results are summarized below.

- Cohort A: Study population excluding subjects with adjudicated AMI and only including subjects with prior history of MACE
- Cohort B: Study population excluding subjects with adjudicated AMI and prior history of MACE
- Cohort C: Study population excluding subjects with adjudicated AMI

Cohort A (Study population excluding subjects with adjudicated AMI and only including subjects with prior history of MACE)
Overall 99th percentile = 45.20 pg/mL for overall (both lithium heparin and serum samples for males and females combined

Pre- and Post-Test Risk and Unadjusted Hazard Ratios

Follow-Up Time Points (Days)	Prevalence of ACM/MACE			Risk of ACM/MACE for patients with cTnI levels >99th Percentile			Risk of ACM/MACE for patients with cTnI levels ≤99th Percentile			Unadjusted Hazard Ratio (95% CI)
	N	Number of ACM/ MACE events	Pre-test risk of ACM/ MACE (%)	N	Number of ACM/ MACE events	Post-test risk of ACM/ MACE (%, 95% CI)	N	Number of ACM /MACE events	Post-test risk of ACM/ MACE (%, 95% CI)	
Lithium Heparin										
30 Days	874	58	6.6	137	13	9.5 (5.9, 14.8)	737	45	6.1 (5.3, 7.0)	1.61 (0.87, 2.98)
90 Days	874	129	14.8	137	36	26.3 (20.4, 33.2)	737	93	12.6 (11.4, 13.9)	2.24 (1.52, 3.29)
182 Days	874	190	21.7	137	49	35.8 (29.0, 43.2)	737	141	19.1 (17.8, 20.5)	2.09 (1.51, 2.90)
365 Days	874	259	29.6	137	67	48.9 (41.4, 56.4)	737	192	26.1 (24.6, 27.6)	2.21 (1.67, 2.92)
Serum										
30 Days	883	60	6.8	131	14	10.7 (6.8, 16.3)	752	46	6.1 (5.3, 7.0)	1.82 (1.00, 3.32)

Follow-Up Time Points (Days)	Prevalence of ACM/MACE			Risk of ACM/MACE for patients with cTnI levels >99th Percentile			Risk of ACM/MACE for patients with cTnI levels ≤99th Percentile			Unadjusted Hazard Ratio (95% CI)
	N	Number of ACM/ MACE events	Pre-test risk of ACM/ MACE (%)	N	Number of ACM/ MACE events	Post-test risk of ACM/ MACE (%, 95% CI)	N	Number of ACM /MACE events	Post-test risk of ACM/ MACE (%, 95% CI)	
90 Days	883	129	14.6	131	35	26.7 (20.2, 32.9)	752	94	12.5 (11.3, 13.8)	2.31 (1.57, 3.41)
182 Days	883	192	21.7	131	48	36.6 (29.0, 43.2)	752	144	19.1 (17.8, 20.5)	2.16 (1.56, 3.00)
365 Days	883	262	29.7	131	65	49.6 (41.5, 56.5)	752	197	26.2 (24.6, 27.6)	2.25 (1.70, 2.98)

Adjusted Hazard Ratios

Sample Matrix	Time Point	N	Adjusted Hazard Ratio (95% CI)
Lithium Heparin Plasma	30 Days	799	1.07 (0.54, 2.09)
	90 Days	799	1.61 (1.06, 2.45)
	182 Days	799	1.59 (1.12, 2.26)
	365 Days	799	1.56 (1.15, 2.12)

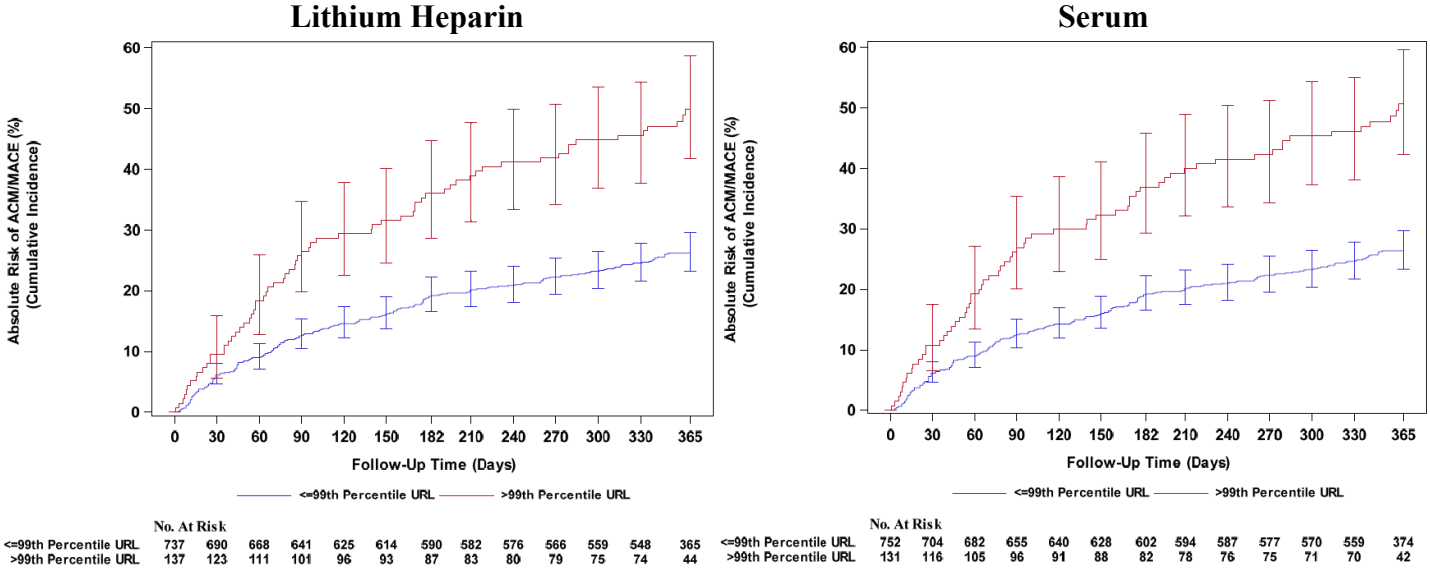
Sample Matrix	Time Point	N	Adjusted Hazard Ratio (95% CI)
Serum	30 Days	807	1.31 (0.68, 2.52)
	90 Days	807	1.79 (1.18, 2.71)
	182 Days	807	1.76 (1.24, 2.49)
	365 Days	807	1.70 (1.25, 2.30)

Summary of Multivariable Cox PH Model Parameters

	Adjusted hazard ratios (95% CI)					
Follow-Up Time Point	Troponin I	Prior Revascularization	Prior Heart Failure	eGFR	Hypertension	Sex
Lithium Heparin						
30 days	1.07 (0.54, 2.09)	0.64 (0.36, 1.12)	1.76 (0.96, 3.22)	1.59 (0.91, 2.79)	1.16 (0.49, 2.73)	1.62 (0.89, 2.96)
90 days	1.61 (1.06, 2.45)	0.82 (0.56, 1.19)	2.20 (1.45, 3.32)	1.52 (1.05, 2.22)	1.57 (0.82, 3.01)	1.42 (0.96, 2.11)
182 days	1.59 (1.12, 2.26)	0.91 (0.67, 1.24)	2.19 (1.57, 3.04)	1.41 (1.03, 1.92)	1.61 (0.95, 2.74)	1.28 (0.93, 1.75)
365 days	1.56 (1.15, 2.12)	0.91 (0.70, 1.19)	2.23 (1.68, 2.97)	1.50 (1.15, 1.96)	1.54 (0.98, 2.42)	1.28 (0.98, 1.68)

Follow-Up Time Point	Adjusted hazard ratios (95% CI)					
	Troponin I	Prior Revascularization	Prior Heart Failure	eGFR	Hypertension	Sex
Serum						
30 days	1.31 (0.68, 2.52)	0.62 (0.36, 1.08)	1.44 (0.81, 2.57)	1.51 (0.86, 2.63)	1.20 (0.51, 2.81)	1.62 (0.89, 2.94)
90 days	1.79 (1.18, 2.71)	0.83 (0.57, 1.21)	1.96 (1.31, 2.94)	1.53 (1.05, 2.22)	1.54 (0.81, 2.96)	1.37 (0.92, 2.02)
182 days	1.76 (1.24, 2.49)	0.95 (0.70, 1.29)	2.16 (1.56, 2.99)	1.36 (1.00, 1.85)	1.60 (0.94, 2.71)	1.28 (0.94, 1.75)
365 days	1.70 (1.25, 2.30)	0.95 (0.73, 1.24)	2.19 (1.65, 2.91)	1.48 (1.13, 1.93)	1.53 (0.98, 2.40)	1.25 (0.96, 1.64)

Kaplan Meier Failure Plot



Event Types Summary (Lithium Heparin Plasma)

Type of Event	Total, N=874 (%)	≤99th Percentile, N=737 (%)	>99th Percentile, N=137 (%)
Survived to day 365 with no ACM/MACE	606	537	69
Loss to follow up	9	8	1
ACM/MACE	259	192	67
Breakdown of ACM/MACE event			
Cardiac Death	10 (3.86)	9 (4.69)	1 (1.49)
Heart Failure Hospitalization	163 (62.93)	113 (58.85)	50 (74.63)
Incident Death	8 (3.09)	5 (2.60)	3 (4.48)
Myocardial Infarction	17 (6.56)	13 (6.77)	4 (5.97)

Type of Event	Total, N=874 (%)	≤99th Percentile, N=737 (%)	>99th Percentile, N=137 (%)
Survived to day 365 with no ACM/MACE	606	537	69
Loss to follow up	9	8	1
ACM/MACE	259	192	67
Myocardial Infarction, Heart Failure Hospitalization	2 (0.77)	1 (0.52)	1 (1.49)
Myocardial Infarction, Urgent Revascularization	7 (2.70)	7 (3.65)	0 (0.00)
Myocardial Infarction, Urgent Revascularization, Heart Failure Hospitalization	1 (0.39)	1 (0.52)	0 (0.00)
Other Death	26 (10.04)	19 (9.90)	7 (10.45)
Urgent Revascularization	24 (9.27)	23 (11.98)	1 (1.49)
Urgent Revascularization, Heart Failure Hospitalization	1 (0.39)	1 (0.52)	0 (0.00)

Cohort B (Study population excluding subjects with adjudicated AMI and prior history of MACE events)

Overall 99th percentile = 45.20 pg/mL for overall (both lithium heparin and serum samples for males and females combined)

Pre- and Post-Test Risk and Unadjusted Hazard Ratios

Follow-Up Time Points (Days)	Prevalence of ACM/MACE			Risk of ACM/MACE for patients with cTnI levels >99th Percentile			Risk of ACM/MACE for patients with cTnI levels ≤99th Percentile			Unadjusted Hazard Ratio (95% CI)
	N	Number of ACM/ MACE events	Pre-test risk of ACM/ MACE (%)	N	Number of ACM/ MACE events	Post-test risk of ACM/ MACE (%, 95% CI)	N	Number of ACM /MACE events	Post-test risk of ACM/ MACE (%, 95% CI)	
Lithium Heparin										
30 Days	1190	9	0.8	53	3	5.7 (2.2, 13.6)	1137	6	0.5 (0.3, 0.8)	10.89 (2.72, 43.53)
90 Days	1190	17	1.4	53	4	7.5 (3.2, 16.7)	1137	13	1.1 (0.9, 1.5)	6.84 (2.23, 20.98)
182 Days	1190	37	3.1	53	7	13.2 (6.9, 23.9)	1137	30	2.6 (2.3, 3.1)	5.28 (2.32, 12.02)
365 Days	1190	58	4.9	53	8	15.1 (8.1, 26.4)	1137	50	4.4 (4.0, 4.9)	3.69 (1.75, 7.79)

Serum										
30 Days	1214	10	0.8	57	2	3.5 (1.0, 11.4)	1157	8	0.7 (0.5, 0.9)	5.08 (1.08, 23.94)
90 Days	1214	19	1.6	57	3	5.3 (1.9, 13.9)	1157	16	1.4 (1.1, 1.7)	3.87 (1.13, 13.28)
182 Days	1214	39	3.2	57	6	10.5 (5.1, 20.5)	1157	33	2.9 (2.5, 3.2)	3.80 (1.59, 9.07)
365 Days	1214	61	5.0	57	7	12.3 (6.2, 22.8)	1157	54	4.7 (4.3, 5.1)	2.75 (1.25, 6.05)

Adjusted Hazard Ratios

Sample Matrix	Time Point	N	Adjusted Hazard Ratio (95% CI)
Lithium Heparin Plasma	30 Days	1169	7.46 (1.65, 33.65)
	90 Days	1169	5.58 (1.69, 18.47)
	182 Days	1169	3.89 (1.63, 9.30)
	365 Days	1169	2.79 (1.28, 6.08)

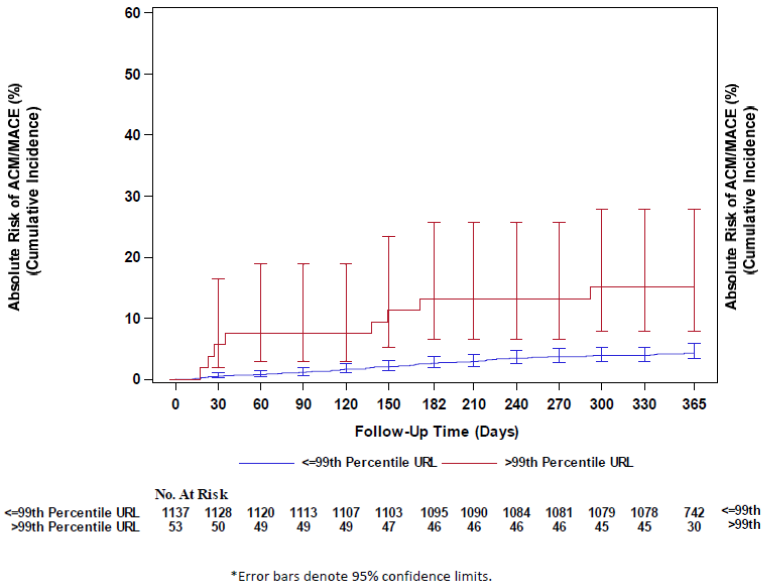
Sample Matrix	Time Point	N	Adjusted Hazard Ratio (95% CI)
Serum	30 Days	1192	2.84 (0.56, 14.38)
	90 Days	1192	2.81 (0.78, 10.12)
	182 Days	1192	2.71 (1.10, 6.69)
	365 Days	1192	2.06 (0.92, 4.64)

Summary of Multivariable Cox PH Model Parameters

	Adjusted hazard ratios (95% CI)			
Follow-Up Time Point	Troponin I	eGFR	Hypertension	Sex
Lithium Heparin				
30 days	7.46 (1.65, 33.65)	2.16 (0.46, 10.08)	2.07 (0.41, 10.54)	1.32 (0.35, 4.94)
90 days	5.58 (1.69, 18.47)	1.73 (0.51, 5.92)	1.21 (0.43, 3.41)	1.52 (0.58, 4.02)
182 days	3.89 (1.63, 9.30)	2.41 (1.09, 5.33)	1.18 (0.58, 2.40)	1.56 (0.81, 3.00)
365 days	2.79 (1.28, 6.08)	2.30 (1.21, 4.40)	1.20 (0.69, 2.09)	1.53 (0.90, 2.58)
Serum				
30 days	2.84 (0.56, 14.38)	4.05 (1.05, 15.68)	2.28 (0.46, 11.30)	1.52 (0.43, 5.40)
90 days	2.81 (0.78, 10.12)	2.49 (0.84, 7.38)	1.41 (0.52, 3.85)	1.43 (0.57, 3.57)
182 days	2.71 (1.10, 6.69)	2.89 (1.37, 6.08)	1.26 (0.63, 2.53)	1.49 (0.78, 2.82)
365 days	2.06 (0.92, 4.64)	2.61 (1.41, 4.84)	1.19 (0.69, 2.05)	1.52 (0.91, 2.53)

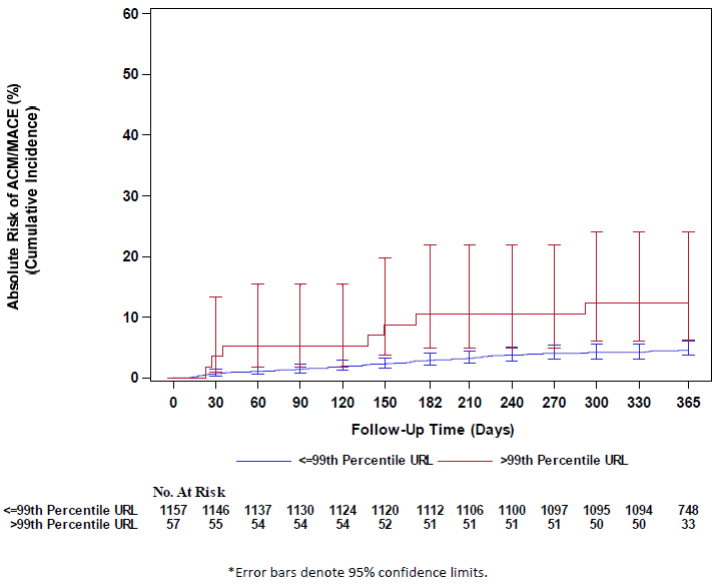
Kaplan Meier Failure Plots

Lithium Heparin



*Error bars denote 95% confidence limits.

Serum



*Error bars denote 95% confidence limits.

Event Types Summary (Lithium Heparin Plasma)

Type of Event	Total, N=1190 (%)	≤99th percentile, N=1137 (%)	>99th percentile, N=53 (%)
Survived to day 365 with no ACM/MACE	1118	1073	45
Loss to follow up	14	14	0
ACM/MACE	58	50	8
Breakdown of ACM/MACE Event			
Cardiac Death	2 (3.45)	2 (4.00)	0 (0.00)
Heart Failure Hospitalization	29 (50.00)	23 (46.00)	6 (75.00)
Myocardial Infarction	4 (6.90)	3 (6.00)	1 (12.50)
Myocardial Infarction, Urgent Revascularization, Cardiac Death	1 (1.72)	0 (0.00)	1 (12.50)
Other Death	14 (24.14)	14 (28.00)	0 (0.00)
Urgent Revascularization	8 (13.79)	8 (16.00)	0 (0.00)

Cohort C (Study population excluding those with adjudicated AMI)
Overall 99th percentile = 45.20 pg/mL for overall (both lithium heparin and serum samples for males and females combined)

Pre- and Post-Test Risk and Unadjusted Hazard Ratios

Follow-Up Time Points (Days)	Prevalence of ACM/MACE			Risk of ACM/MACE for patients with cTnI levels >99th Percentile			Risk of ACM/MACE for patients with cTnI levels ≤99th Percentile			Unadjusted Hazard Ratio (95% CI)
	N	Number of ACM/ MACE events	Pre-test risk of ACM/ MACE (%)	N	Number of ACM/ MACE events	Post-test risk of ACM/ MACE (%, 95% CI)	N	Number of ACM /MACE events	Post-test risk of ACM/ MACE (%, 95% CI)	
Lithium Heparin										
30 Days	2064	67	3.2	190	16	8.4 (5.5, 12.6)	1874	51	2.7 (2.4, 3.1)	3.21 (1.83, 5.64)
90 Days	2064	146	7.1	190	40	21.1 (16.4, 26.6)	1874	106	5.7 (5.1, 6.2)	4.03 (2.80, 5.80)
182 Days	2064	227	11.0	190	56	29.5 (24.0, 35.6)	1874	171	9.1 (8.5, 9.8)	3.66 (2.71, 4.95)
365 Days	2064	317	15.4	190	75	39.5 (33.3, 46.0)	1874	242	12.9 (12.2, 13.6)	3.64 (2.81, 4.72)
Serum										
30 Days	2097	70	3.3	188	16	8.5 (5.6, 12.8)	1909	54	2.8 (2.5, 3.2)	3.13 (1.79, 5.47)
90 Days	2097	148	7.1	188	38	20.2 (15.6, 25.8)	1909	110	5.8 (5.3, 6.3)	3.79 (2.62, 5.48)
182 Days	2097	231	11.0	188	54	28.7 (23.3, 34.9)	1909	177	9.3 (8.7, 9.9)	3.49 (2.57, 4.74)
365 Days	2097	323	15.4	188	72	38.3 (32.2, 44.8)	1909	251	13.1 (12.5, 13.8)	3.44 (2.65, 4.47)

Adjusted Troponin I Hazard Ratios

Sample Matrix	Time Point	N	Adjusted Hazard Ratio (95% CI)
Lithium Heparin Plasma	30 Days	1968	1.55 (0.84, 2.89)
	90 Days	1968	2.03 (1.36, 3.01)
	182 Days	1968	1.97 (1.42, 2.73)
	365 Days	1968	1.85 (1.39, 2.47)

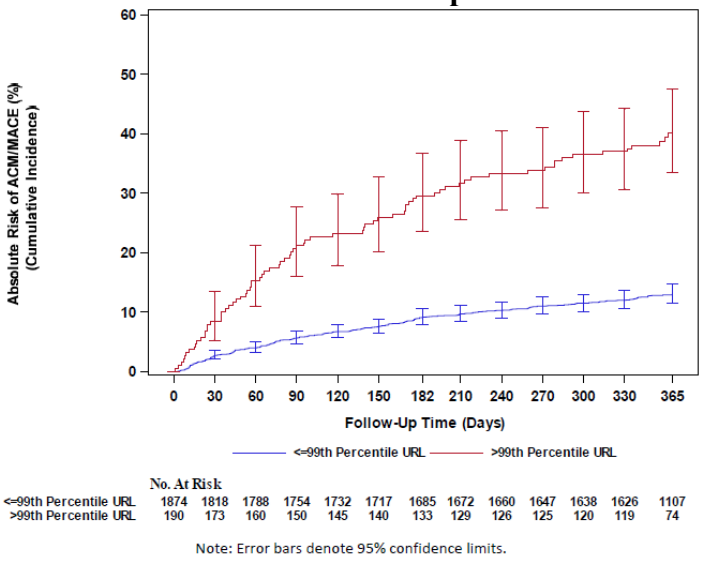
Sample Matrix	Time Point	N	Adjusted Hazard Ratio (95% CI)
Serum	30 Days	1999	1.68 (0.91, 3.09)
	90 Days	1999	2.11 (1.42, 3.13)
	182 Days	1999	2.04 (1.48, 2.83)
	365 Days	1999	1.91 (1.44, 2.54)

Summary of Multivariable Cox PH Model Parameters

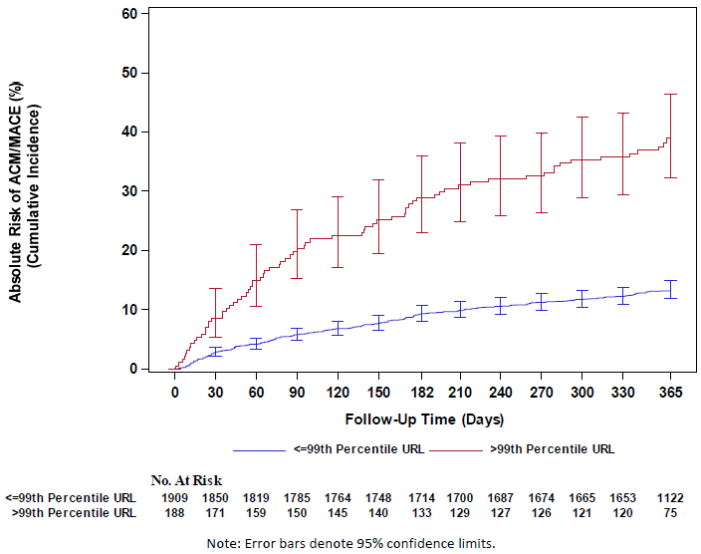
	Adjusted hazard ratios (95% CI)					
Follow-Up Time Point	Troponin I	Prior Revascularization	Prior Heart Failure	eGFR	Hypertension	Sex
Lithium Heparin						
30 days	1.55 (0.84, 2.89)	1.19 (0.71, 2.02)	3.62 (2.07, 6.33)	1.74 (1.02, 2.98)	1.87 (0.86, 4.05)	1.62 (0.94, 2.79)
90 days	2.03 (1.36, 3.01)	1.39 (0.98, 1.97)	4.35 (2.96, 6.38)	1.60 (1.11, 2.29)	1.93 (1.12, 3.31)	1.48 (1.03, 2.14)
182 days	1.97 (1.42, 2.73)	1.50 (1.13, 1.98)	3.79 (2.80, 5.12)	1.56 (1.16, 2.08)	1.85 (1.23, 2.80)	1.37 (1.03, 1.82)
365 days	1.85 (1.39, 2.47)	1.47 (1.16, 1.88)	3.80 (2.94, 4.92)	1.63 (1.27, 2.10)	1.75 (1.24, 2.45)	1.37 (1.08, 1.74)
Serum						
30 days	1.68 (0.91, 3.09)	1.22 (0.73, 2.03)	2.99 (1.74, 5.13)	1.78 (1.05, 3.02)	2.05 (0.95, 4.41)	1.71 (0.99, 2.92)
90 days	2.11 (1.42, 3.13)	1.43 (1.01, 2.03)	3.81 (2.62, 5.55)	1.65 (1.15, 2.36)	2.01 (1.17, 3.44)	1.45 (1.01, 2.07)
182 days	2.04 (1.48, 2.83)	1.54 (1.17, 2.03)	3.66 (2.72, 4.92)	1.54 (1.15, 2.06)	1.89 (1.25, 2.85)	1.38 (1.04, 1.83)
365 days	1.91 (1.44, 2.54)	1.52 (1.20, 1.93)	3.67 (2.85, 4.73)	1.64 (1.28, 2.10)	1.73 (1.24, 2.42)	1.36 (1.07, 1.73)

Kaplan Meier Failure Plots

Lithium Heparin



Serum



Event Types Summary (Lithium Heparin Plasma)

Type of Event	Total, N=2064 (%)	≤99th percentile, N=1874 (%)	>99th percentile, N=190 (%)
Survived to day 365 with no ACM/MACE	1724	1610	114
Loss to follow up	23	22	1
ACM/MACE	317	242	75
Breakdown of ACM/MACE Event			
Cardiac Death	12 (3.79)	11 (4.55)	1 (1.33)
Heart Failure Hospitalization	192 (60.57)	136 (56.20)	56 (74.67)
Incident Death	8 (2.52)	5 (2.07)	3 (4.00)
Myocardial Infarction	21 (6.62)	16 (6.61)	5 (6.67)
Myocardial Infarction, Heart Failure Hospitalization	2 (0.63)	1 (0.41)	1 (1.33)
Myocardial Infarction, Urgent Revascularization	7 (2.21)	7 (2.89)	0 (0.00)
Myocardial Infarction, Urgent Revascularization, Cardiac Death	1 (0.32)	0 (0.00)	1 (1.33)
Myocardial Infarction, Urgent Revascularization, Heart Failure Hospitalization	1 (0.32)	1 (0.41)	0 (0.00)

Type of Event	Total, N=2064 (%)	≤99th percentile, N=1874 (%)	>99th percentile, N=190 (%)
Survived to day 365 with no ACM/MACE	1724	1610	114
Loss to follow up	23	22	1
ACM/MACE	317	242	75
Breakdown of ACM/MACE Event			
Other Death	40 (12.62)	33 (13.64)	7 (9.33)
Urgent Revascularization	24 (10.09)	23 (12.81)	1 (1.33)
Urgent Revascularization, Heart Failure Hospitalization	1 (0.32)	1 (0.41)	0 (0.00)

D Clinical Cut-Off:

The clinical cut-off of the Atellica IM High-Sensitivity Troponin I (TnIH) assay was established in K171566.

E Expected Values/Reference Range:

The expected values/reference range of the Atellica IM High-Sensitivity Troponin I (TnIH) assay were established in K171566.

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.