K082699

AUG 19 2009

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 521-3338

Contact Person: Jane Phillips

Date Prepared: 07/09/2009

Device Name

Proprietary name:
1.) Elecsys® Troponin I Immunoassay
2.) Elecsys® Troponin I STAT Immunoassay
3.) Elecsys® PreciControl Troponin
4.) Elecsys® Troponin I CalSet
5.) Elecsys® Troponin I STAT CalSet

Common name:
1.) Troponin I Immunoassay
2.) Troponin I STAT Immunoassay
3.) PreciControl Troponin
4.) Troponin I CalSet
5.) Troponin I STAT CalSet

Classification name:
1.) Immunoassay Method, Troponin Subunit
2.) Immunoassay Method, Troponin Subunit
3.) Multi-Analyte Controls, All Kinds (assayed)
4.) Calibrator, Secondary
5.) Calibrator, Secondary

Description

1.) The Elecsys Troponin I immunoassay is a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection. Results are determined using a calibration curve that is generated specifically on each instrument by a 2 point calibration and a master curve provided with the reagent bar code.
2.) The Elecsys Troponin I STAT immunoassay is a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection. Results are determined using a calibration curve that is generated specifically on each instrument by a 2 point calibration and a master curve provided with the reagent bar code.
3.) The Elecsys PreciControl Troponin is a lyophilized product consisting of human serum with added Troponin T and Troponin I in two concentration ranges. During manufacture, the analytes are spiked into the matrix at the desired concentration levels.
4.) The Elecsys Troponin I CalSet is a lyophilized product consisting of human serum with added Troponin I in two concentration ranges. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.
5.) The Elecsys Troponin I STAT CalSet is a lyophilized product consisting of human serum with added Troponin I in two concentration ranges. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Note: The reagent, calibrator, and quality control materials are all packaged separately.

Intended Use / Indications for Use

Elecsys Troponin I Immunoassay: Immunoassay for the in vitro quantitative determination of cardiac troponin I in human serum and plasma. The Elecsys Troponin I assay is intended to aid in the diagnosis of myocardial infarction.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Elecsys and MODULAR Analytics E170 immunoassay analyzers.

Elecsys Troponin I STAT Immunoassay: Immunoassay for the in vitro quantitative determination of cardiac troponin I in human serum and plasma. The Elecsys Troponin I STAT assay is intended to aid in the diagnosis of myocardial infarction.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Elecsys analyzers.

Elecsys PreciControl Troponin is used for quality control of the Elecsys Troponin I and Elecsys Troponin I STAT immunoassays on the Elecsys and MODULAR Analytics E170 Analyzers.

The **Elecsys Troponin I CalSet** is used for calibrating the quantitative Elecsys Troponin I assay on the Elecsys and MODULAR Analytics E170 analyzers.

The **Elecsys Troponin I STAT CalSet** is used for calibrating the quantitative Elecsys Troponin I STAT assay on the Elecsys analyzers.

Substantial equivalence

The Elecsys Troponin I and Troponin I STAT Test Systems are substantially equivalent to other devices legally marketed in the United States.

1.) Elecsys Troponin I and Troponin I STAT Immunoassays are equivalent to the Beckman Coulter Access AccuTnI Immunoassay (K021814).
2.) Elecsys PreciControl Troponin is equivalent to Elecsys PreciControl Cardiac II (K072437).
3.) Elecsys Troponin I CalSet and Troponin I STAT CalSet are equivalent to Elecsys proBNP II CalSet (K072437).

Device Comparison – Immunoassay

The following table compares the Elecsys Troponin I STAT test system with the predicate device (K021814).

Substantial equivalence – comparison to the predicate device

Immunoassay		
Feature	**Elecsys Troponin I STAT Assay**	**Beckman Coulter Access AccuTnI (K021814) Predicate**
Intended Use / Indication for Use	Immunoassay for the in vitro quantitative determination of cardiac troponin I in human serum and plasma. The Elecsys Troponin I STAT assay is intended to aid in the diagnosis of myocardial infarction. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Elecsys analyzers.	The Access AccuTnI assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the Access Immunoassay Systems to aid in the diagnosis and treatment of myocardial infarction and cardiac muscle damage. Cardiac troponin I determination aids in the risk stratification of patients with unstable angina or non-ST segment elevation acute coronary syndromes with respect to relative risk of mortality, myocardial infarction, or increased probability of ischemic events requiring urgent revascularization procedures.
Assay Protocol	Sandwich Principle	Sandwich Principle
Detection Protocol	Electrochemiluminescence	Chemiluminescence

Immunoassay, continued		
Feature	**Elecsys Troponin I STAT Assay**	**Beckman Coulter Access AccuTnI (K021814) Predicate**
Traceability / Standardization	Standardized against the Beckman Coulter Access AccuTnI assay.	Not stated.
Calibration Interval	Calibration must be performed once per reagent lot using fresh reagent. Renewed calibration: • After 1 month (28 days) when using the same reagent lot • After 7 days (when using the same reagent kit on the analyzer)	An active calibration curve is required for all tests. For the Access AccuTnI assay, calibration is required every 56 days.
Sample Type	Human serum and plasma	Human serum and plasma
Reagent Stability	Unopened • Up to stated expiration date stored at 2-8°C After Opening • 4 weeks at 2-8°C • 2 weeks on the analyzers	Unopened • Up to stated expiration date stored at 2-8°C After Opening • Stable at 2 – 10°C for 56 days after initial use
Calibrator	Elecsys Troponin I STAT CalSet	Access AccuTnI Calibrators
Controls	Elecsys PreciControl Troponin	Commercial control material
Expected values	Age 20 – 79, expected value < 0.3 ng/mL: Values less than 0.3 ng/mL will be reported as "< 0.3 ng/mL".	Age 19 – 88: 97.5th percentile: 0.03 ng/mL 99th percentile: 0.04 ng/mL
Instrument	Elecsys Analyzers	Access Immunoassay Systems
Measuring Range	0.30 – 25.00 µg/L (ng/mL)	0.01 – 100.00 µg/L (ng/mL)

Immunoassay, continued			
Feature	**Elecsys Troponin I STAT Assay**	**Elecsys Troponin I STAT Assay**	**Beckman Coulter Access AccuTnI (K021814) Predicate**
Precision	US Site 1 Repeatability (within-run) 4.8% CV @ 0.323 ng/mL 3.3% CV @ 0.496 ng/mL 2.2% CV @ 0.627 ng/mL 1.7% CV @ 21.400 ng/mL 4.2% CV @ 0.439 ng/mL 2.9% CV @ 17.800 ng/mL Intermediate Precision (between-run and between-day) 8.9% CV @ 0.323 ng/mL 5.9% CV @ 0.496 ng/mL 5.3% CV @ 0.627 ng/mL 3.2% CV @ 21.400 ng/mL 6.7% CV @ 0.439 ng/mL 3.6% CV @ 17.800 ng/mL US Site 2 Repeatability 3.0% CV @ 0.483 ng/mL 3.9% CV @ 0.329 ng/mL 1.8% CV @ 2.180 ng/mL 2.1% CV @ 0.691 ng/mL 4.0% CV @ 0.376 ng/mL 2.3% CV @ 17.300 ng/mL Intermediate Precision 4.0% CV @ 0.483 ng/mL 5.7% CV @ 0.329 ng/mL 2.4% CV @ 2.180 ng/mL 2.9% CV @ 0.691 ng/mL 5.3% CV @ 0.376 ng/mL 2.6% CV @ 17.300 ng/mL	EU Site 1 Repeatability 2.5% CV @ 0.447 ng/mL 4.1% CV @ 0.347 ng/mL 0.7% CV @ 7.600 ng/mL 3.1% CV @ 0.498 ng/mL 2.6% CV @ 0.395 ng/mL 0.6% CV @ 17.600 ng/mL Intermediate Precision 6.1% CV @ 0.447 ng/mL 8.0% CV @ 0.347 ng/mL 4.3% CV @ 7.600 ng/mL 5.4% CV @ 0.498 ng/mL 4.8% CV @ 0.395 ng/mL 1.9% CV @ 17.600 ng/mL	Within Run: 4.03% CV @ 0.56 ng/mL 3.06% CV @ 7.31 ng/mL 3.29% CV @ 30.55 ng/mL 4.42% CV @ 0.42 ng/mL 3.42% CV @ 1.34 ng/mL Between Run: 2.97% CV @ 0.56 ng/mL 4.12% CV @ 7.31 ng/mL 6.07% CV @ 30.55 ng/mL 2.71% CV @ 0.42 ng/mL 2.75% CV @ 1.34 ng/mL Total Imprecision: 5.01% CV @ 0.56 ng/mL 5.13% CV @ 7.31 ng/mL 6.90% CV @ 30.55 ng/mL 5.19% CV @ 0.42 ng/mL 4.39% CV @ 1.34 ng/mL

Immunoassay, continued		
Feature	**Elecsys Troponin I STAT Assay**	**Beckman Coulter Access AccuTnI (K021814) Predicate**
Cut-off	0.3 ng/mL	0.5 ng/mL
Hook Effect	1,000 ng/mL	1,920 ng/mL
Method Comparison	N = 114 Range = 0.35 – 21.54 ng/mL Passing/Bablok: y = 0.7954x + 0.2187 tau = 0.8058 Linear Regression: y = 0.7878x + 0.3204 r = 0.9519 Deming: y = 0.8198x + 0.2168 r = 0.9465	N = 157 Range = 0.03 – 44.89 Intercept = -1.039 ng/mL Slope = 0.932 r = 0.980
Limit of Blank	Studies done and LoB is less than LoQ (0.3 ng/mL)	Not given
Limit of Detection / Analytical Sensitivity	Studies done and LoB is less than LoQ (0.3 ng/mL)	= 0.01 ng/mL (LDL)
Limit of Quantitation / Functional Sensitivity	= 0.3 ng/mL at 10% CV	= 0.03 ng/mL at 20% CV = 0.06 ng/mL at 10% CV

Immunoassay, continued		
Feature	**Elecsys Troponin I STAT Assay**	**Beckman Coulter Access AccuTnI (K021814) Predicate**
Limitations	• No interference from bilirubin if less than 25 mg/dL • No interference from hemoglobin if less than 400 mg/dL • No interference from Intralipid if less than 1500 mg/dL • No interference from biotin if less than 30 ng/mL • No interference from rheumatoid factor up to 1500 IU/mL • In patients receiving high biotin doses > 5 mg/day, sample should not be taken until 8 hours after administration. • Rare occurrence of interference from high titers of anti-streptavidin and ruthenium • Use in conjunction with patient medical history, clinical exam and other findings	• No interference from bilirubin up to 40 mg/dL • No interference from fibrinogen up to 1000 mg/dL • No interference from triglycerides up to 1000 mg/dL • No interference from hemoglobin up to 500 mg/dL • No interference from human serum albumin up to 6000 mg/dL

Device Comparison – Control

The following table compares the Elecsys Troponin I Assay (18 Minute) with the predicate device (K021814).

Substantial equivalence – comparison to the predicate device

Immunoassay		
Feature	**Elecsys Troponin I Assay**	**Beckman Coulter Access AccuTnI (K021814) Predicate**
Intended Use / Indication for Use	Immunoassay for the in vitro quantitative determination of cardiac troponin I in human serum and plasma. The Elecsys Troponin I assay is intended to aid in the diagnosis of myocardial infarction. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Elecsys and MODULAR Analytics E170 immunoassay analyzers.	The Access AccuTnI assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the Access Immunoassay Systems to aid in the diagnosis and treatment of myocardial infarction and cardiac muscle damage. Cardiac troponin I determination aids in the risk stratification of patients with unstable angina or non-ST segment elevation acute coronary syndromes with respect to relative risk of mortality, myocardial infarction, or increased probability of ischemic events requiring urgent revascularization procedures.
Assay Protocol	Sandwich Principle	Sandwich Principle
Detection Protocol	Electrochemiluminescence	Chemiluminescence

Immunoassay, continued		
Feature	**Elecsys Troponin I Assay**	**Beckman Coulter Access AccuTnI (K021814) Predicate**
Traceability / Standardization	Standardized against the Beckman Coulter Access AccuTnI assay.	Not stated.
Calibration Interval	Calibration must be performed once per reagent lot using fresh reagent. Renewed calibration: • After 1 month (28 days) when using the same reagent lot • After 7 days (when using the same reagent kit on the analyzer)	An active calibration curve is required for all tests. For the Access AccuTnI assay, calibration is required every 56 days.
Sample Type	Human serum and plasma	Human serum and plasma
Reagent Stability	Unopened • Up to stated expiration date stored at 2-8°C After Opening • 4 weeks at 2-8°C • 2 weeks on the analyzers	Unopened • Up to stated expiration date stored at 2-8°C After Opening • Stable at 2 – 10°C for 56 days after initial use
Calibrator	Elecsys Troponin I CalSet	Access AccuTnI Calibrators
Controls	Elecsys PreciControl Troponin	Commercial control material
Expected values	Age 20 – 79 expected value < 0.3 ng/mL: Values less than 0.3 ng/mL will be reported as "< 0.3 ng/mL".	Age 19 – 88: 97.5th percentile: 0.03 ng/mL 99th percentile: 0.04 ng/mL
Instrument	Elecsys and MODULAR Analytics E170 Analyzers	Access Immunoassay Systems
Measuring Range	0.30 – 25.00 µg/L (ng/mL)	0.01 – 100 µg/L (ng/mL)

Immunoassay, continued		
Feature	**Elecsys Troponin I Assay**	**Beckman Coulter Access AccuTnI (K021814) Predicate**
Precision	Repeatability (within run) 5.3% CV @ 0.322 ng/mL 5.2% CV @ 0.425 ng/mL 2.7% CV @ 17.6 ng/mL 7.0% CV @ 0.340 ng/mL 2.6% CV @ 18.0 ng/mL Intermediate Precision (between-run and between-day) 8.7% CV @ 0.322 ng/mL 7.3% CV @ 0.425 ng/mL 4.7% CV @ 17.6 ng/mL 8.0% CV @ 0.340 ng/mL 4.4% CV @ 18.0 ng/mL	Within Run: 4.03% CV @ 0.56 ng/mL 3.06% CV @ 7.31 ng/mL 3.29% CV @ 30.55 ng/mL 4.42% CV @ 0.42 ng/mL 3.42% CV @ 1.34 ng/mL Between Run: 2.97% CV @ 0.56 ng/mL 4.12% CV @ 7.31 ng/mL 6.07% CV @ 30.55 ng/mL 2.71% CV @ 0.42 ng/mL 2.75% CV @ 1.34 ng/mL Total Imprecision: 5.01% CV @ 0.56 ng/mL 5.13% CV @ 7.31 ng/mL 6.90% CV @ 30.55 ng/mL 5.19% CV @ 0.42 ng/mL 4.39% CV @ 1.34 ng/mL
Cut-off	0.3 ng/mL	0.5 ng/mL

Immunoassay, continued		
Feature	**Elecsys Troponin I Assay**	**Beckman Coulter Access AccuTnI (K021814) Predicate**
Hook Effect	1000 ng/mL	1,920 ng/mL
Method Comparison	N = 115 Range = 0.34 – 24.62 ng/mL Passing/Bablok: y = 0.9743x - 0.00172 tau = 0.9616 Linear Regression: y = 0.9934x - 0.0623 r = 0.9934 Deming Regression y = 1x – 0.1080 r = 0.9971	N = 157 Range = 0.03 – 44.89 Intercept = -1.039 ng/mL Slope = 0.932 r = 0.980
Limit of Blank	Studies done and LoB is less than LoQ (0.3 ng/mL)	Not given
Limit of Detection / Analytical Sensitivity	Studies done and LoD is less than LoQ (0.3 ng/mL)	0.01 ng/mL (LDL)
Limit of Quantitation / Functional Sensitivity	= 0.3 ng/mL at 10% CV	0.03 ng/mL at 20% CV 0.06 ng/mL at 10% CV

Immunoassay, continued		
Feature	**Elecsys Troponin I Assay**	**Beckman Coulter Access AccuTnI (K021814) Predicate**
Limitations	• No interference from bilirubin if less than 25 mg/dL • No interference from hemoglobin if less than 400 mg/dL • No interference from Intralipid if less than 1500 mg/dL • No interference from biotin if less than 30 ng/mL • No interference from rheumatoid factor up to 1500 IU/mL • In patients receiving high biotin doses > 5 mg/day, sample should not be taken until 8 hours after administration. • Rare occurrence of interference from high titers of anti-streptavidin and ruthenium • Use in conjunction with patient medical history, clinical exam and other findings	• No interference from bilirubin up to 40 mg/dL • No interference from fibrinogen up to 1000 mg/dL • No interference from triglycerides up to 1000 mg/dL • No interference from hemoglobin up to 500 mg/dL • No interference from human serum albumin up to 6000 mg/dL

Device Comparison – Control

The following table compares the Elecsys PreciControl Troponin with the predicate device (K072437).

PreciControl Comparison		
Characteristic	**Elecsys PreciControl Troponin I**	**Elecsys PreciControl Cardiac II (K072437) Predicate**
Intended Use	Used for quality control of the Elecsys Troponin I and Elecsys Troponin I STAT immunoassays on the Elecsys and MODULAR Analytics E170 Analyzers.	Used for quality control of specified immunoassays on the Elecsys and **cobas e** immunoassay analyzers.
Levels	Two	Two
Format	Lyophilized, human serum	Lyophilized, human serum
Analyte Concentration	Troponin T: approx. 0.03 ng/mL and 2.5 ng/mL Troponin I: 0.4 ng/mL and 18 ng/mL	CK-MB: approx. 5 and 50 ng/ml Digitoxin: approx 17 and 38 ng/mL (not for use in U.S.) Digoxin: approx. 1.2 and 3 ng/ml Myoglobin: approx. 80 and 1000 ng/ml NT-proBNP: approx. 0.15 and 5 ng/ml
Stability	Unopened: store at 2 – 8°C up to expiration date Reconstituted: 5 hrs at 20 – 25°C (on analyzer) 4 days at 2 – 8°C 3 months at -20°C (freeze only once) After thawing – use only once	Unopened: store at 2 – 8°C up to expiration date Reconstituted: 3 hrs at 20 – 25°C (on analyzer) 3 days at 2 – 8°C 3 months at -20°C (freeze only once) After thawing – use only once
Handling	Dissolve carefully the contents of one bottle by adding exactly 2.0 mL of distilled water and allow stand closed for 60 minutes to reconstitute. Mix carefully, avoiding the formation of foam.	Dissolve carefully the contents of one bottle by adding exactly 2.0 mL of distilled water and allow stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam.

Device Comparison – CalSet

The following table compares the Elecsys Troponin I CalSet with the predicate device (K072437).

CalSet Comparison		
Characteristic	**Elecsys Troponin I CalSet**	**Elecsys proBNP II CalSet (K072437) Predicate**
Intended Use	The Elecsys Troponin I CalSet is used for calibrating the quantitative Elecsys Troponin I assay on the Elecsys and MODULAR Analytics E170 analyzers.	Used for calibrating the quantitative Elecsys proBNP II assay on Elecsys and **cobas e** immunoassay analyzers.
Levels	Two	Two
Format	Lyophilized, human serum	Lyophilized, equine serum
Analyte Concentration	Troponin I: 0.4 ng/mL and 30 ng/mL	proBNP: 16.6 pmol/L and 320 pmol/L
Stability	Unopened: • Store at 2 – 8°C until expiration date. Reconstituted: • 2 – 8°C: 4 days • -20°C: 3 months (freeze only once) • On the Elecsys and MODULAR Analytics E170 analyzers: use only once	Unopened: • Store at 2 – 8°C until expiration date. Reconstituted: • 2 – 8°C: 2 weeks • -20°C: 3 months (freeze only once) • On Elecsys 1010/2010 and cobas e411 analyzers at 20 – 25°C: up to 5 hours • On MODULAR ANALYTICS E170 and cobas e601 analyzers: use only once
Handling	Dissolve contents of one bottle by adding exactly 1.0 mL of distilled water and allow to stand closed for 60 minutes to reconstitute. Mix carefully, avoiding the formation of foam.	Dissolve contents of one bottle by adding exactly 1.0 mL of distilled water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam.

Device Comparison – STAT CalSet

The following table compares the Elecsys Troponin I STAT CalSet with the predicate device (K072437).

CalSet Comparison		
Characteristic	**Elecsys Troponin I STAT CalSet**	**Elecsys proBNP II CalSet (K072437) Predicate**
Intended Use	The Elecsys Troponin I STAT CalSet is used for calibrating the quantitative Elecsys Troponin I STAT assay on the Elecsys analyzers.	Used for calibrating the quantitative Elecsys proBNP II assay on Elecsys and **cobas e** immunoassay analyzers.
Levels	Two	Two
Analyte Concentration	Troponin I: 0.4 ng/mL and 30 ng/mL	CK-MB: approx. 5 and 50 ng/ml Digitoxin: approx 17 and 38 ng/mL (not for use in U.S.) Digoxin: approx. 1.2 and 3 ng/ml Myoglobin: approx. 80 and 1000 ng/ml NT-proBNP: approx. 0.15 and 5 ng/ml
Format	Lyophilized, human serum	Lyophilized, equine serum
Stability	Unopened: • Store at 2 – 8°C until expiration date. Reconstituted: • 2 – 8°C: 4 days • -20°C: 3 months (freeze only once) • On Elecsys analyzers: up to 5 hours	Unopened: • Store at 2 – 8°C until expiration date. Reconstituted: • 2 – 8°C: 2 weeks • -20°C: 3 months (freeze only once) • On Elecsys 1010/2010 and cobas e411 analyzers at 20 – 25°C: up to 5 hours • On MODULAR ANALYTICS E170 and cobas e601 analyzers: use only once

Device Comparison – STAT CalSet

The following table compares the Elecsys Troponin I STAT CalSet with the predicate device (K072437).

CalSet Comparison, continued		
Characteristic	**Elecsys Troponin I STAT CalSet**	**Elecsys proBNP II CalSet (K072437) Predicate**
Handling	Dissolve contents of one bottle by adding exactly 1.0 mL of distilled water and allow to stand closed for 60 minutes to reconstitute. Mix carefully, avoiding the formation of foam.	Dissolve contents of one bottle by adding exactly 1.0 mL of distilled water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Roche Diagnostics
Centralized Diagnostics
c/o Dr. Jane Phillips
Regulatory Affairs Principal
9115 Hague Road
Indianapolis, IN 46250

AUG 19 2009

Re: k082699
Trade Name: Roche Elecsys® Troponin I Immunoassay, Roche Elecsys® Troponin I STAT Immunoassay, Roche Elecsys® PreciControl Troponin, Roche Elecsys® Troponin I CalSet, Roche Elecsys® Troponin I STAT CalSet
Regulation Number: 21 CFR §862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test
Regulatory Class: Class II
Product Codes: MMI, JJY, JIT
Dated: June 17, 2009
Received: June 18, 2009

Dear Dr. Phillips:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use – Elecsys Troponin I Immunoassay

510(k) Number: 082699

Device Name: **Elecsys Troponin I Immunoassay**

Indication for Use: Immunoassay for the in vitro quantitative determination of cardiac troponin I in human serum and plasma. The Elecsys Troponin I assay is intended to aid in the diagnosis of myocardial infarction.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Elecsys and MODULAR Analytics E170 immunoassay analyzers.

Prescription Use **XXX** (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K082699

Indications for Use – Elecsys Troponin I STAT Immunoassay

510(k) Number: 082699

Device Name: **Elecsys Troponin I STAT Immunoassay**

Indication for Use: Immunoassay for the in vitro quantitative determination of cardiac troponin I in human serum and plasma. The Elecsys Troponin I STAT assay is intended to aid in the diagnosis of myocardial infarction.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Elecsys analyzers.

Prescription Use **XXX** (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

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Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K082699

Indications for Use – Elecsys PreciControl Troponin

510(k) Number: 082699

Device Name: **Elecsys PreciControl Troponin**

Elecsys PreciControl Troponin is used for quality control of the Elecsys Troponin I and Elecsys Troponin I STAT immunoassays on the Elecsys and MODULAR Analytics E170 Analyzers.

Prescription Use **XXX** And/Or Over the Counter Use ____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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510(k) K082699

Indications for Use – Elecsys Troponin I CalSet

510(k) Number: 082699

Device Name: **Elecsys Troponin I CalSet**

Elecsys Troponin I CalSet is used for calibrating the quantitative Elecsys Troponin I assay on the Elecsys and MODULAR Analytics E170 analyzers.

Prescription Use **XXX** (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

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Evaluation and Safety

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Indications for Use – Elecsys Troponin I STAT CalSet

510(k) Number: 082699

Device Name: **Elecsys Troponin I STAT CalSet**

Elecsys Troponin I STAT CalSet is used for calibrating the quantitative Elecsys Troponin I STAT assay on the Elecsys analyzers.

Prescription Use **XXX** And/Or Over the Counter Use____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K082699