DEC 3 0 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Troponin I (TnI-Ultra) Assay for Bayer ADVIA Centaur®

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K053020

1. Intended Use

For *in vitro* diagnostic use in the quantitative determination of cardiac troponin I in serum, heparinized or EDTA plasma using ADVIA Centaur® system.

Cardiac troponin I determinations aid in the diagnosis of acute myocardial infarction and in the risk stratification of patients with non-ST segment elevation acute coronary syndromes with respect to relative risk mortality, myocaridal infarction or increased probability of ischemic events requiring urgent revascularization procedures.

The ADVIA Centaur® TnI-Ultra Calibrator is for the in vitro diagnostic use in the calibration of the TnI-Ultra assay on the ADVIA Centaur® system.

2. Predicate Devices

Product Name	Reagent REF	Calibrator REF
ACS:180® and ADVIA Centaur® Cardiac Troponin I (cTnI) Assay	ACS:180 07572636 (50 test) 00370639 (300 test) ADVIA Centaur 07640356 (100 tests) 0595168 (500 tests)	Kit component

3. Device / Method

Product Name	Reagent REF	Calibrator REF
ADVIA Centaur® TnI-Ultra Assay	02789602 (100 tests) 02790309 (500 tests)	Kit component

4. Imprecision

ADVIA Centaur® TnI-Ultra			**ADVIA Centaur® cTnI***			**ACS:180 cTnI***	
Level (ng/mL)	Total CV (%)		Level (ng/mL)	Total CV (%)		Level (ng/mL)	Total CV (%)
0.1	4.6		0.94	6.6		0.8	7.5
0.24	3.5		2.38	5.0		1.37	6.7
0.85	2.7		3.72	3.0		15.73	5.0
3.91	2.8		8.08	4.4		33.83	5.3
14.47	3.4		13.29	3.9		43.01	5.8
37.8	3.5		15.95	3.9			
			43.62	3.6			

ADVIA Centaur® TnI-Ultra		**ADVIA Centaur® cTnI***		**ACS:180 cTnI***	
Level (ng/mL)	Within-run CV(%)	Level (ng/mL)	Within-run CV(%)	Level (ng/mL)	Within-run CV(%)
0.1	3.2	0.94	4.6	0.8	4.4
0.24	2.6	2.38	2.3	1.37	4.2
0.85	1.6	3.72	2.6	15.73	2.2
3.91	1.5	8.08	1.9	33.83	2.3
14.47	1.5	13.29	1.4	43.01	3.0
37.8	1.8	15.95	2.3		
		43.62	2.4		

* data from instructions for use

The troponin I concentration at a total CV of 10% was determined to be 0.042 ng/mL.

Functional Sensitivity (20% total C.V.) was calculated as <0.008 ng/mL for ADVIA Centaur® TnI-Ultra Assay.

5. Correlation (Y= ADVIA Centaur® TnI-Ultra, X = Comparative System)

Specimen type Regression method	Comparative System (X)	N	Regression Equation	Sample Range (ng/mL)
Serum Passing & Bablok	Bayer ADVIA Centaur	346	1.10X - 0.045	0.1 to 34.8
Linear Regression	Bayer ADVIA Centaur	346	1.26X - 0.52 r = 0.975	0.1 to 34.8
Serum Passing & Bablok	ACS:180	334	1.2X - 0.032	0.1 to 30.9
Linear Regression	ACS:180	334	1.4X - 0.51 r = 0.967	0.1 to 30.9

In order to demonstrate equivalence between devices, the following correlations were generated using clinically significant troponin doses less than 4.0 ng/mL only.

Specimen type Regression method	Comparative System (X)	N	Regression Equation	Sample Range (ng/mL)
Serum Passing & Bablok	Bayer ADVIA Centaur	229	1.08X - 0.02	0.1 to 4.0
Linear Regression	Bayer ADVIA Centaur	229	1.04X + 0.04 r = 0.946	0.1 to 4.0
Serum Passing & Bablok	ACS:180	230	1.17X - 0.006	0.1 to 4.0
Linear Regression	ACS:180	230	1.13X + 0.068 r = 0.943	0.1 to 4.0

Further comparison of clinical utility was done by comparing doses from ADVIA Centaur TnI-Ultra to ACS:180 and ADVIA Centaur cTnI. The WHO criteria cut-off of 0.9 ng/mL was used for this evaluation.

ADVIA Centaur TnI- Ultra		ADVIA Centaur cTnI	
		< 0.9 ng/mL	≥ 0.9 ng/mL
	< 0.9 ng/mL	101	2
	≥ 0.9 ng/mL	7	261
	Concordance = 97.6%		

ADVIA Centaur TnI- Ultra		ACS:180 cTnI	
		< 0.9 ng/mL	≥ 0.9 ng/mL
	< 0.9 ng/mL	101	2
	≥ 0.9 ng/mL	20	236
	Concordance = 93.9%		

6. Interfering substances

	Interference Concentration	Recovery (ng/mL)		%
Interference		**Expected**	**Observed**	**Deviation**
Hemoglobin	500 mg/dL	1.17	1.15	-1.7
Lipemia	1000 mg/dL	1.06	1.05	-0.9
Icterus Conjugated bilirubin	20 mg/dL	0.85	0.81	-4.7
Icterus Unconjugated bilirubin	20 mg/dL	1.16	1.07	-7.8
Human immunoglobulin	12 g/dL	1.10	1.04	-5.4

7. Analytical Range

0.008 ng/mL to 50 ng/mL.

8. Minimum Detectable Concentration

ADVIA Centaur® TnI-Ultra (ng/mL)	ADVIA Centaur® TnI (ng/mL)
0.008	0.07

9. 99th Percentile Distribution and Functional Sensitivity

Based on 648 serum samples from apparently healthy donors, the upper 99th percentile Troponin I value is 0.044 ng/mL.

10. Expected Results

The AMI cutoff value of ≥ 0.9 ng/mL is based on the data for the Bayer HealthCare ACS:180 Troponin I assay, to which ADVIA Centaur® TnI-Ultra method is equivalent.

Method	% Sensitivity	% Specificity
ACS:180 cTnI	97.3	97.0
No. Patients (n)	112	166
95% Confidence Interval	92.4 – 99.4	93.1 – 99.0
Alternate troponin I method	96.4	93.4
No. Patients (n)	112	166
95% Confidence Interval	91.1 – 99.0	88.5 – 96.7

December 28, 2005

Date

Andres Holle
Manager Regulatory Affairs
Bayer Corporation
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914-524-3494

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 3 0 2005

Mr. Andres Holle
Manager Regulatory Affairs
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511 Benedict Avenue
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Re: k053020
Trade/Device Name: Troponin I Ultra Assay and Calibrator for the ADVIA Centaur® System
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI, JIT
Dated: October 21, 2005
Received: October 28, 2005

Dear Mr. Holle:

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
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

510(k) Number (if known): K053020

Device Name: Troponin I Ultra Assay and Calibrator for the ADVIA Centaur® System

Indications For Use:

The ADVIA Centaur® TnI-Ultra (TnI-Ultra) method is for *in vitro* diagnostic use in the quantitative determination of cardiac Troponin I in human serum and heparinized and EDTA plasma. Cardiac troponin I determinations aid in the diagnosis of acute myocardial infarction and in the risk stratification of patients with non-ST segment elevation acute coronary syndromes with respective to relative risk mortality, myocardial infarction or increased probability of ischemic events requiring urgent revascularization procedures.

The ADVIA Centaur® TnI-Ultra Calibrator is for the in vitro diagnostic use in the calibration of the TnI-Ultra assay on the ADVIA Centaur® system.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

TnI-Ultra Calibrator

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K053020