DEC 14 2005

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

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: __K052503_____

1. Intended Use

The ADVIA IMS® Troponin I Ultra (TnI-Ultra) method is for in vitro diagnostic use to quantitatively measure the cardiac Troponin I in human serum and plasma (lithium heparin). When used in conjunction with other clinical data such as presenting symptoms and diagnostic procedures, measurements of cardiac Troponin I aid in the diagnosis of acute myocardial infarction (AMI) and in the risk stratification of patients with 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.

2. Predicate Device

Product Name	Reagent REF	Calibrator REF
Bayer ACS:180® cTnI Assay	07572636 (50 tests) 00370639 (300 tests)	Included with Reagents

3. Device / Method

Product Name	Reagent REF	Calibrator REF
ADVIA IMS® Troponin I Ultra (TnI-Ultra) Assay	02157487	06504521

4. Imprecision

ADVIA IMS® TnI-Ultra Assay	
Level (ng/mL)	Total CV(%)
1.55	5.7
14.06	2.2
32.93	2.7
0.21	5.4
9.05	2.7

Bayer ACS:180 cTnI Assay	
Level (ng/mL)	Total CV(%)
0.80	7.5
1.37	6.7
15.73	5.0
33.83	5.3
43.01	5.8

5. Correlation (Y= ADVIA IMS®, X = Bayer ACS:180®)

Specimen type	Comparative System (X)	N	Regression Equation	Syx (ng/mL)	R	Sample Range (ng/mL)
Serum (Passing Bablok)	Bayer ACS:180	97	1.01 * X - 0.01	N/A		0.01 to 49.6
Serum (Linear Regression)	Bayer ACS:180	97	0.90 * X + 0.43	2.64	0.954	0.01 to 49.6

6. Interfering substances

	Interference Conc.	**Recovery (ng/mL)**		**%**
Interference	**mg/dL**	**Expected**	**Observed**	**Deviation**
Albumin	6500	9.32	9.5	1.9
Bilirubin	20	22.9	20.6	-3.3
Hemoglobin	500	22.9	21.0	-4.7
Triglyceride	1000	22.7	20.1	-3.8

7. Analytical Range

0.01 ng/mL (0.01 µg/L) to 50 ng/mL (50 µg/L)

8. Minimum Detectable Concentration

ADVIA IMS® TnI-Ultra (ng/mL)	Bayer ACS:180® cTnI (ng/mL)
0.01	0.10

9. 99th Percentile Distribution and Functional Sensitivity

Based on 337 serum samples from apparently healthy donors, the upper 99th percentile Troponin I value is 0.04 ng/mL.

Functional Sensitivity (10% total C.V.) is 0.03 ng/mL for ADVIA IMS® TnI-Ultra Assay.

10. Expected Results

The AMI cutoff value is based on the data for the Bayer HealthCare ACS:180 Troponin I assay, to which ADVIA IMS® TnI-Ultra method is equivalent.

Sample	N	Range µg/L (ng/mL)
Healthy Blood Donors	337	< 0.04
AMI patients	112	≥ 1.5

Andres Holle
Manager Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 14 2005

Mr. Andres Holle
Manager, Regulatory Affairs
Bayer HealthCare Diagnostics Division
511 Benedict Avenue
Tarrytown, NY 10591

Re: k052503
Trade/Device Name: Troponin I Ultra Assay and
Calibrator for the ADVIA IMS® 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: November 7, 2005
Received: November 9, 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): K052503

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

Indications For Use:

The ADVIA IMS® Troponin I Ultra (TnI-Ultra) method is for in vitro diagnostic use to quantitatively measure the cardiac Troponin I in human serum and plasma (lithium heparin). When used in conjunction with other clinical data such as presenting symptoms and diagnostic procedures, measurements of cardiac Troponin I aid in the diagnosis of acute myocardial infarction (AMI) and in the risk stratification of patients with 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.

The ADVIA IMS® TnI-Ultra Calibrator is for the in vitro diagnostic use in the calibration of the TnI-Ultra assay on the ADVIA IMS® 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)

Carol Benson

Division of Clinical Laboratory Devices

510(k) K052503