K063845

510(k) Summary

DEC 07 2007

Submitter information

Contact person: Philip Liu
Manager, Regulatory Affairs & Compliance

Address: Siemens Medical Solutions Diagnostics
(formerly Bayer HealthCare, LLC, Diagnostics Division)
511 Benedict Avenue
Tarrytown, NY 10591

Phone: 914-524-2443
914-524-2500 (fax)

Date summary prepared: November 30, 2007

Device Trade or Proprietary Name: ADVIA® Chemistry Total Bilirubin_2

Device Common/Usual Name or Classification Name: Total Bilirubin Reagent/Test System

Classification Number/Class: JFM/Class II

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: k063845

Predicate Devices:

	Predicate Device
Device Name	ADVIA® IMS
Common name	Total Bilirubin
510(k) Number	K992399
Manufacturer	Bayer HealthCare LLC

Device Description:

The ADVIA Chemistry Total Bilirubin_2 is used for the *in vitro* quantitative determination of total bilirubin in human serum and plasma on the ADVIA® Chemistry Systems. The proposed labeling indicates the ADVIA Chemistry Total Bilirubin_2 reagents can be used on the ADVIA Chemistry Systems 1650, 1800, 2400, and 1200.

The Total Bilirubin_2 assay is based on a chemical oxidation method, utilizing vanadate as the oxidizing agent. Total bilirubin (conjugated and unconjugated) is oxidized by vanadate at about pH 2.9 to produce biliverdin. In the presence of detergent and vanadate, both conjugated and unconjugated bilirubin are oxidized. This oxidation reaction causes a decrease in the optical density of the yellow color, which is specific to bilirubin. The decrease in optical density at 451/545 nm is proportional to the total bilirubin concentration in the sample. The concentration is measured as an endpoint reaction.

Statement of Intended Use:

The ADVIA Chemistry Total Bilirubin_2 assay is for *in vitro* diagnostic use in the quantitative determination of total bilirubin in human serum and plasma on the ADVIA® Chemistry Systems. Such measurements are used in the diagnosis and treatment of hemolytic, biliary, and liver disorders, including hepatitis and cirrhosis.

Comparison to the Predicate Device:

Similarities

	ADVIA Chemistry Total Bilirubin_2	ADVIA IMS *(predicate device)*
Intended Use	For the quantitative determination of total bilirubin	For the quantitative determination of total bilirubin
Specimen Type	Human serum or plasma (lithium heparin)	Human serum or plasma (lithium heparin)
Reaction Type	Colorimetric endpoint	Colorimetric endpoint
Calibration	Single point	Single point
Expected Values*	0.2 – 1.2 mg/dL	0.2 – 1.2 mg/dL

* Tietz NW, Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Company; 1995:88-91

Differences

	ADVIA Chemistry Total Bilirubin_2	ADVI IMS *(predicate device)*
Principle	Vanadate oxidation	Diazotized sulfanilic acid with blank
Reagents	Two liquid reagents contained in system specific packaging	One lyophilized reagent, diluent, and one liquid reagent contained in system specific packaging
Standardization	AACC Reference Method	AACC Reference Method

Performance:

Substantial equivalence was demonstrated by testing several performance characteristics including imprecision, method comparison, interfering substances, serum/plasma equivalency, and analytical range. The following tables summarize the precision (total), interfering substances, analytical range, and method comparison results.

All of the evaluation studies gave acceptable results compared to the predicate device. These studies support that the ADVIA Chemistry Total Bilirubin_2 assay is substantially equivalent to the ADVIA IMS Total Bilirubin assay that is currently marketed.

Imprecision (Serum)

ADVIA Chemistry 1650/1800		ADVIA Chemistry 2400		ADVIA Chemistry 1200		ADVIA IMS	
Level (mg/dL)	Total CV (%)	Level (mg/dL)	Total CV (%)	Level (mg/dL)	Total CV (%)	Level (mg/dL)	Total CV (%)
1.0	2.0	1.0	4.7	1.1	3.6	0.8	8.2
7.1	2.6	7.2	2.3	7.6	1.3	6.7	2.1
15.4	3.2	15.5	1.6	14.7	1.4	16.7	2.4
22.1	1.2	21.8	1.0	22.1	1.4	--	--
27.5	1.1	27.1	1.5	27.6	1.7	--	--

Correlation (y = ADVIA Chemistry Total Bilirubin_2, x = comparison system)

Specimen type, System (y)	Comparison System (x)	N	Regression Equation	Syx (mg/dL)	r	Sample Range (mg/dL)
Serum, ADVIA 1650	ADVIA IMS	118	y= 0.925x + 0.12	0.42	0.998	0.2 - 26.8
Serum, ADVIA 2400	ADVIA 1650	119	y= 0.999x - 0.02	0.19	1.000	0.3 - 24.4
Serum, ADVIA 1200	ADVIA 1650	119	y= 1.036x - 0.05	0.21	1.000	0.3 - 24.4

Interfering Substances

Interfering Substance	Interfering Substance Conc. (mg/dL)	Total Bilirubin Conc. (mg/dL)			Effect (% change)		
		ADVIA 1650/1800	ADVIA 2400	ADVIA 1200	ADVIA 1650/1800	ADVIA 2400	ADVIA 1200
Ascorbic acid	50	1.30	1.29	1.33	-1.16	-4.65	0.00
Hemoglobin	1000	1.18	1.22	1.36	6.80	-2.1	7.0
Lipids (Triglycerides)	750	1.11	1.11	1.12	8.6	6.8	7.2

Analytical Range (Serum/Plasma)

ADVIA 1650/1800	0.1 - 35.0 mg/dL
ADVIA 2400	0.1 - 35.0 mg/dL
ADVIA 1200	0.1 - 35.0 mg/dL

Conclusions:

The ADVIA Chemistry Total Bilirubin_2 assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the Bayer ADVIA IMS Total Bilirubin method (K992399).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 0 7 2007

Bayer Healthcare, LLC
c/o Dr. Philip Liu
Manager, Regulatory Affairs and Compliance
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: k063845
Trade Name: Advia Chemistry Total Bilirubin 2
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (Total or Direct) Test System.
Regulatory Class: Class II
Product Code: JFM
Dated: November 30, 2007
Received: December 04, 2007

Dear Dr. Liu:

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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
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): k063845

Device Name: ADVIA CHEMISTRY TOTAL BILIRUBIN_2

Indications For Use:

For *in vitro* diagnostic use in the quantitative determination of total bilirubin in human serum and plasma on the ADVIA Chemistry Systems. Such measurements are used in the diagnosis and treatment of hemolytic, biliary, and liver disorders, including hepatitis and cirrhosis.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K063845