SEP - 9 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
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: K032525

1. Intended Use

The *Bayer ADVIA Centaur* assay is an automated immunoassay analyzer designed to perform in vitro diagnostic immunochemical assay analysis on clinical specimens. The system menu will include endocrine, anemia, allergy, reproductive, cardiovascular, oncology, adrenal, bone metabolism, therapeutic drug, and infectious disease assays. All assays are based on chemiluminescent technology.

2. Predicate Device

Proprietary Name: ACS: Centaur Analyzer
Common name: Automated Immunoassay Analyzer
Classification name: Photometric Analyzer for Clinical Use
Classification number: 21 CFR 862.2160, Class I
510(k) Number: K971418

3. Device Information

Proprietary Name: Bayer ADVIA Centaur Analyzer
Common name: Automated Immunoassay Analyzer
Classification name: Photometric Analyzer for Clinical Use
Classification number: 21 CFR 862.2160, Class I

4. Device Description

The ADVIA Centaur system is a stand-alone, continuous operation, immunochemistry analyzer. The system performs the following functions:

- Aspirates and dispenses samples
- Performs dilutions
- Adds reagents
- Incubates reaction vessels
- Separates solid and liquid wastes
- Measures photon emissions
- Performs data reduction
- Collects and maintains patient demographics and results

5. Summary of Technological Characteristics

Assays that are dedicated for use on the ADVIA Centaur utilize acridinium ester as label and paramagnetic particles as the solid phase. The ADVIA Centaur measures the amount of light emitted during the chemiluminescent reaction. There is a direct relationship between the amount of light emitted and the amount of antigen in the patient sample. The system will measure both competitive binding assays and sandwich assays.

The ADVIA Centaur system uses a Master Curve and a two-point, user-initiated calibration to calibrate all the assays. The Master Curve and the two-point calibration system eliminate the need to measure a full standard curve with each assay or to run calibrators each time the assay is run. The system stores the calibration for the interval specified in the assay product inserts.

A comparison table of Technological Features is included below:

Feature	ACS Centaur V1.0 (ACS Next Generation)	ADVIA Centaur V2.5
Principles of Operation	- Chemiluminescence using magnetic-particle solid phase and chemiluminescent label	same
Optical System	- PMT used in photon counting mode	same
Temp control	- Reactions are controlled at 37°C	same
	- Reagent Storage:	
	- Reagents stored at 4°C to 8°C	same
Dispense System	- Automated pipetting of samples and reagents	same
	- Precision syringes (sample and reagent)	same
	Sample Probe :	
	· Air pressure fluid sensing	same
	· Air pressure disposable tip sensing	same
	· Clog detection mechanism to alert operator to clogged sample probe	same
	Reagent Probes:	
	· No level sense; probe sent to bottom of container	same
	· Fluid monitoring during aspiration	same
Reagent and Sample Handling	- Samples: 5 tube racks hold sample tube. The Sample Input, In-Process and Output Queue holds up to 180 samples; Tube size selected on sample tube rack using an encoded barcode.	same

	- Assay Reagents: Reagent Tray with 30 positions; Refrigeration; Reagent Pack contains both Solid Phase and Tracer Reagent in separate wells	same
	- Ancillary Reagents: Reagent Compartment with 15 positions; Refrigeration	same
Test Processing	Random Access and Batch	same
	- Sample scheduling optimized for throughput; Continuous Operation	same
Assay Protocols	- 7.5 minute incubation, single step	same
	- 20 minute incubation, single step	same
	- 7.5 - 20 minute incubation, two step	same
	- 20 - 20 minute incubation, two Step	same
Human Interface - data Output	- 17" Color Monitor with Graphical User Interface	same
	- External printers	same
	- Serial bi-directional LIS Interface	same
	- Audible (adjustable) beeper	same
	- Computer LIS Interface	same
	- External Modem for Remote Diagnostics Interface	same
Human Interface - data Input	- 101 key keyboard	same
	- Hand-held barcode reader	same
	- Stationary barcode scanners for id of patient samples	same
	- Moving Barcode reader for primary reagents	same
	- Computer LIS Interface	same
		LIS Software, additional features
Human Interface - data analysis	- Automated data reduction	same
	- Assay-specific data reduction	same
QC Software	- Stored control results	same
	- L-J plotting	same
	- Statistical enhancements	same
	- Compatibility with CCD QC Reporting	same
		Added New Features to QC Functionality
Specimens	- Serum or plasma, sample cups or primary tubes may be used	same
	- Dilutions allowed on a per-assay basis	same
	- Capability of Dilution of Samples Requiring Pretreatment	same
Disposables	- Sample cups	same
	- Reaction cuvettes	same
	- Cuvette loading and unloading allowed during run	same
	- Reagent I & 2 status tracked and displayed	same

	- Time to First Result: 15 min., 30 min., 60 min. depending upon assay protocol	same
	. On-board supplies for 1000 tests (cuvettes,water,waste capacity)	same
		Added diagnostic tools
Software	Unix based graphical User interface, Multiple distributed real-time computing platforms with capabilities to communicate to LIS and LAS systems.	Same, except for additional features as follows:
		New Reports-maintenance,event log, reagent tracking.
		Screen Saver added
		New Exit queue status window
Hardware Improvements	ACS Centaur System	Same, except for enhancements as follows:
		New UI Module with increased capacity
		Hitachi/ Unviersal rack option added
		High Resolution Barcode Scanner (LS4000i) released.

8/8/03

Andres Holle
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

SEP - 9 2003

Mr. Andres Holle
Manager, Regulatory Affairs
Bayer HealthCare LLC
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511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: k032525
Trade/Device Name: ADVIA® Centaur
Regulation Number: 21 CFR 862.1117
Regulation Name: B-type natriuretic peptide test system
Regulatory Class: Class II
Product Code: NBC; LOQ; MOI; NIG; LTK; DHK; KLT; JHX; JFT; JIT; LFM; KXT; CHP; DBF; CGN; JJX; CEC; CGJ; LCD; LPS; CEP; DDR; DIS; LGR; JLS; CFT; LTJ; LFX; LCR; LGD; MMI; KHQ; GWG; JHI; CDZ; LGS; DGC; JLW; JZO; LEH; DKB; CDD; JJE
Dated: July 23, 2003
Received: August 15, 2003

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number:

Device Name: ADVIA® Centaur

Indications for Use:

The *Bayer ADVIA Centaur* is an automated immunoassay analyzer designed to perform in vitro diagnostic immunochemical assay analysis on clinical specimens. The system menu will include endocrine, anemia, allergy, reproductive, cardiovascular, oncology, adrenal, bone metabolism, therapeutic drug, and infectious disease assays. All assays are based on chemiluminescent technology.

Carol C Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032525

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-CounterUse _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)