JUN 2 7 2002

K021532

Bayer Diagnostics

ASC:180 and ADVIA Centaur C-peptide Calibrator

Section 2: Summary of Safety and Effectiveness

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. Submitter Information

Contact person:	Kenneth T. Edds Ph.D.
Address: 511 Benedict Ave. Tarrytown, NY 10591	Bayer Diagnostics Corporation
Phone: FAX: e-mail:	(914) 524-2446 (914) 524-2500 ken.edds.b.@bayer.com
Date Summary Prepared:	April 29, 2002

2. Device Information

Proprietary Name:	ADVIA Centaur and ACS:180 C-peptide Calibrator
Common Name:	Calibrator for immunoassay analyte
Classification Name: Class: CFR: Product Code:	Calibrator §862.1150. Class II 862.1150 75 JIT

3. Predicate Device Information

Name:	AIA-PACK C-Peptide Calibrator Set
Manufacturer:	TOSOH Corporation TOSOH Kyobashi Building 3-2-4 Kyobashi, Chuo-ku, Tokyo 104-0031,
Japan	Phone: +81-(3)-3275-1221 Fax: +81-(3)-3275-1214
510(k) Number:	K951848

4. Device Description

The ACS:180 and ADVIA Centaur C-peptide Calibrator is a citric acid buffered saline with casein and preservatives (micro-protect).

5. Statement of Intended Use

For use in calibrating the ADVIA Centaur and ACS:180 C-peptide immunoassays on the automated analyzers marketed by Bayer Corporation.

6. Summary of Technological Characteristics

The ADVIA Centaur and ACS:180 C-peptide Calibrators are similar to the TOSOH Corporation AIA-PACK C-Peptide Calibrator Set (K971998) in the indications for use, and reference method for standardization, WHO 84/510. In the ACS:180 and ADVIA Centaur C-peptide calibrator a buffer base is used to replace the protein matrix used in the TOSOH Corporation AIA-PACK C-Peptide Calibrator Set.

7. Accuracy and Precision

The commercial control dose data represented in this document was generated using the calibrators for each respective C-peptide immunoassay.

Substantial equivalence to the AIA-PACK C-Peptide Calibrator Set is based on comparison of the control accuracy and precision of the ADVIA Centaur and ACS:180 to the predicate device.

System	Sample ID	Mean	Within Run %CV	Total %CV	% Recovery vs TOSOH
AIA TOSOH	Level 1	1.71	2.8	5.7	
	Level 2	5.23	2.0	5.8	
ACS:180					
	Level 1	1.63	4.3	9.8	95.3
	Level 2	5.22	3.2	6.1	99.8
	Level 3	11.72	3.6	7.6	NA
ADVIA Centaur	Level 1	1.43	3.7	6.1	83.6
	Level 2	4.88	4.0	5.1	93.3
	Level 3	10.60	4.1	6.2	NA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 7 2002

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: k021532
Trade/Device Name: Bayer Diagnostics ACS:180 and ADVIA Centaur C-peptide Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: May 3, 2002
Received: May 10, 2002

Dear Dr. Edds:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021532

Device Name: Bayer Diagnostics ACS:180 and ADVIA Centaur C-peptide Calibrator

Indications for Use:

The ACS:180 and ADVIA Centaur C-peptide calibrators are used for calibrating the ACS:180 and ADVIA Centaur C-peptide Immunoassays.

The ACS:180 and ADVIA Centaur C-peptide are sandwich, chemiluminescence immunoassay for the quantitative determination of C-peptide in human serum for use on the automated analyzer marketed by Bayer Corporation. The ACS:180 and ADVIA Centaur C-peptide Immunoassays can be used to aid in the diagnosis and treatment of patients with abnormal insulin secretion including diabetes mellitus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

Dean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021532