MAR 1 5 2002

K020217

Bayer Diagnostics
ASC:180 Intact Parathyroid Hormone (iPTH) Immunoassay
Section 2: Summary of Safety and Effectiveness

This *Summary of Safety and Effectiveness* has been prepared in accordance with the requirements of 21 CFR 807.92.

1. Submitter Information

Contact person:	Kenneth T. Edds, Ph.D.
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Date Summary Prepared:	January 9, 2002

2. Device Information

Proprietary Name:	ACS:180 and ADVIA Centaur Intact PTH Immunoassay
Common Name:	iPTH
Classification:	immunological test system
Class:	Class II Device
CFR:	21 CFR 862.1545
Product Code:	CEW

3. Predicate Device Information

Name:	Nichols Institute Diagnostics Intact Parathyroid Hormone (PTH) kit / Nichols IRMA Intact PTH
Manufacturer:	Nichols Institute Diagnostics 33608 Ortega Highway San Juan Capistrano, Ca
510(k) Number:	K954418

4. Device Description

The ACS:180 Intact PTH assay is a two-site "sandwich" immunoassay using direct, chemiluminometric technology, which uses two affinity purified goat polyclonal antibodies specific for the PTH molecules. The first antibody is directed toward the N-terminal (1-34) antigenic PTH domain and is labeled with acridinium ester (AE). The second antibody is directed toward the C-terminal (39-84) antigenic domain and is labeled with biotin. Patient sample (calibrator or control material) is incubated, for 5 minutes at 37°C with the Lite Reagent (LR) material that contains both the capture and tracer antibody conjugates. An immuno-complex is formed between the intact PTH in the sample and the two antibody conjugates. Subsequently, Solid Phase (SP) reagent is added and incubated for 2.5 minutes at 37°C. The immuno-complex molecule is captured by the streptavidin coated paramagnetic particles in the SP. Following incubation the unbound antibody conjugates are washed away. The chemiluminescent of the immuno-complex signal is measured in a luminometer. A sample with low intact PTH will have a minimum amount of bound AE label, while samples containing high levels of intact PTH will have maximum label complex bound. Thus, a direct relationship exists between the amount of intact PTH present in the sample and the amount of relative light units (RLUs) detected by the system.

5. Statement of Intended Use

The ACS:180 and ADVIA Centaur Intact PTH Immunoassay is intended for the quantitative determination of intact parathyroid hormone in human EDTA plasma on the automated analyzers marketed by Bayer Corporation. Measurements of intact PTH levels are used to aid in the differential diagnosis of hyperparathyroidism, hypoparathyroidism, or hypercalcemia of malignancy.

6. Summary of Technological Characteristics

The ACS:180 Intact PTH immunoassay is similar to the predicate device Nichols IRMA Intact PTH Assay Kit in the assay principles and performance characteristics. The ACS:180 Intact PTH immunoassay differs from the predicate device in its intended use on an automated analyzer as compared to a manual coated tube technique. In the automated method a chemiluminogenic (acridinium ester) labeled antibody replaces the radiolabeled antibody in the manual method. The automated method also offers a shorter incubation time, 7.5 minutes compared to 22 hours.

7. Method Comparison

The data represented in this document is organized into two components:

1. Comparison of the ACS:180 iPTH to the predicate device Nichols Institute Diagnostics Intact Parathyroid Hormone (PTH) kit (K954418) results in section 4.
2. Comparison of the ADVIA Centaur to the ACS:180 used transference. Transference is a method recommended by NCCLS (C28-A, How to Define Reference Intervals in the Clinical Laboratory; Approved Guideline). This document discusses and provides guidelines for "transference of s reference interval for an analyte measured by a different analytical system, different method or different instrument. Results are in section 5.

ACS:180 iPTH vs. Nichols Institute Diagnostics Intact Parathyroid Hormone (PTH)
Substantial equivalence to the Nichols Institute Diagnostics Intact Parathyroid Hormone (PTH) kit, cleared under K954418, is based on method comparison using 100 EDTA plasma samples in the range of 5.4 to 1969 pg/mL. The results using a linear regression are listed below:

y (ACS:180) = 0.976 x (Nichols IRMA) - 17 pg/mL
Correlation coefficient (r) = 0.985
N = 100
$S_{y.x}$ = 66

ADVIA Centaur iPTH vs. ACS:180 iPTH
For 268 EDTA plasma samples in the range of 9.3 to 1981 pg/mL, the relationship between the ADVIA Centaur iPTH assay and the ACS:180 iPTH assay is described by the equation:

ADVIA Centaur iPTH = 1.03 (ACS:180 iPTH) + 3.36 pg/mL
Correlation Coefficient (r) = 0.994
N = 252
$S_{y.x}$ = 31

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 15 2002

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

Re: k020217
Trade/Device Name: Bayer Diagnostics ACS:180 and ADVIA Centaur Intact PTH Assay
Regulation Number: 21 CFR 862.1545; 21 CFR 862.1660; 21 CFR 862.1150
Regulation Name: Parathyroid hormone test system; Quality control Material (assayed and unassayed); Calibrator
Regulatory Class: Class II; Class I, Class II
Product Code: CEW; JJX; JIT
Dated: January 18, 2002
Received: January 22, 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): K020217

Device Name: Bayer Diagnostics ACS:180 and ADVIA Centaur Intact PTH Assay

Indications for Use:

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(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)**

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020217