

K981839

AUG 12 1998

Company Confidential  
**Summary of Safety and Effectiveness**

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

**1. Submitter Information**

Contact person: William J. Pignato

Address: Chiron Diagnostics Corporation  
63 North Street  
Medfield, MA 02052

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e-mail: william.pignato@chirondiag.com

Date Summary Prepared: May 18, 1998

**2. Device Information**

Proprietary Name: ACS:Centaur PSA2 Immunoassay  
Common Name: PSA Immunoassay  
Classification Name: Reclassified to Class II, classification number unknown

**3. Predicate Device Information**

Name: ACS:180 PSA2 Immunoassay  
Manufacturer: Chiron Diagnostics  
510(k) Number: P920030 & P020030/S1 (note reclassified to class II)

**4. Device Description**

Prostate-specific antigen (PSA) is a single-chain glycoprotein normally found in the cytoplasm of the epithelial cells lining the acini and ducts of the prostate gland. PSA is a neutral serine protease of 240 amino acids involved in the lysis of seminal coagulum.

PSA is detected in the serum of males with normal, benign hypertrophic, and malignant prostate tissue. PSA is not detected in the serum of males without prostate tissue (because of radical prostatectomy or cystoprostatectomy) or in the serum of most females. The fact that PSA is unique to prostate tissue makes it a suitable marker for monitoring men with cancer of the prostate. PSA is also useful for determining possible recurrence after therapy when used in conjunction with other diagnostic indices.

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Measurement of serum PSA levels is not recommended as a screening procedure for the diagnosis of cancer because elevated PSA levels also are observed in patients with benign prostatic hypertrophy. However, studies suggest that the measurement of PSA in conjunction with digital rectal examination (DRE) and ultrasound provide a better method of detecting prostate cancer than DRE alone.

PSA levels increase in men with cancer of the prostate, and after radical prostatectomy PSA levels routinely fall to the undetectable range. If prostatic tissue remains after surgery or metastasis has occurred, PSA appears to be useful in detecting residual and early recurrence of tumor. Therefore, serial PSA levels can help determine the success of prostatectomy, and the need for further treatment, such as radiation, endocrine or chemotherapy, and in the monitoring of the effectiveness of therapy.

## **5. Statement of Intended Use**

The Chiron Diagnostics ACS:Centaur PSA2 Immunoassay is for the quantitative determination of prostate specific antigen in serum to aid in the management of cancer patients in whom changing concentrations of PSA are observed using the Chiron Diagnostics ACS:Centaur Automated Chemiluminescence Systems.

## **6. Summary of Technological Characteristics**

The Chiron Diagnostics ACS:Centaur PSA2 immunoassay is a two-site immunoassay using direct chemiluminometric technology, which uses constant amounts of two antibodies. The first antibody, in the Lite Reagent, is a purified polyclonal sheep anti-PSA antibody labeled with acridinium ester. The second antibody, in the Solid Phase, is a monoclonal mouse anti-PSA antibody covalently coupled to paramagnetic particles. A direct relationship exists between the amount of PSA present in the patient sample and the amount of relative light units (RLU's) detected by the system.

## **7. Performance Data**

### **Sensitivity**

The ACS:Centaur Immunoassay measures PSA concentration up to 135 ng/mL with a minimum detectable concentration of 0.06 ng/mL.

### **Accuracy**

For 287 samples in the range of .07 to 111.25 ng/mL, the correlation between the ACS:Centaur PSA2 and the ACS:180 PSA2 is described by the equation:

$$\text{ACS:Centaur PSA2} = 0.97 (\text{ACS:180 PSA2}) + 0.19 \text{ ng/mL}$$

Correlation coefficient (r) = 0.99



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 12 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. Thomas F. Flynn  
Manager, Regulatory Affairs  
& Compliance  
Chiron Diagnostics Corporation  
63 North Street  
Medfield, Massachusetts 02052

Re: K981839/S1  
Trade Name: ACS:Centaur PSA2 Immunoassay  
Regulatory Class: II  
Product Code: LTJ  
Dated: August 3, 1998  
Received: August 4, 1998

Dear Mr. Flynn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

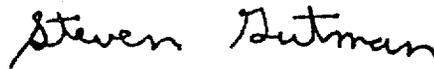
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

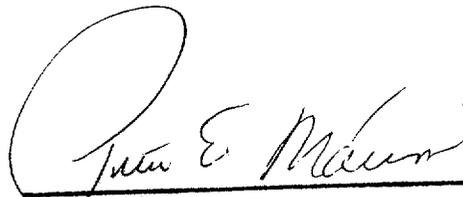
Enclosure

510(k) Number (if known): K981839

Device Name: Chiron Diagnostics ACS:Centaur PSA2 Immunoassay

Indications for Use:

The Chiron Diagnostics ACS:Centaur PSA2 Immunoassay is for the quantitative determination of prostate specific antigen in serum to aid in the management of cancer patients in whom changing concentrations of PSA are observed using the Chiron Diagnostics ACS:Centaur Automated Chemiluminescence Systems.

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

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)