

K981592

JUL 7 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: Thomas F. Flynn
Address: Chiron Diagnostics Corporation
63 North Street
Medfield, MA 02052
Phone: (508) 359-3877
FAX: (508) 359-3885
e-mail: thomas.flynn@chirondiag.com
Date Summary Prepared: April 20, 1998

2. Device Information

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

3. Predicate Device Information

Name: ACS:180 AFP Immunoassay
Manufacturer: Chiron Diagnostics
510(k) Number: P920030 (note reclassified to class II)

4. Device Description

The Chiron Diagnostics ACS:Centaur AFP 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 rabbit anti-AFP antibody labeled with acridinium ester. The second antibody, in the Solid Phase, is a monoclonal mouse anti-AFP antibody covalently coupled to paramagnetic particles. A direct relationship exists between the amount of AFP present in the patient sample and the amount of relative light units (RLU's) detected by the system.

5. Statement of Intended Use

The intended use of ACS:Centaur AFP Immunoassay is for the quantitative determination of alpha-fetoprotein (AFP) in the following:

- * human serum and in amniotic fluid from specimens obtained at 15 to 20 weeks gestation, as an aid in detecting open neural defects (NTD) when used in conjunction with ultrasonography and amniography testing,
- * human serum, as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures, using the Chiron Diagnostics ACS:Centaur Automated Chemiluminescence System.

6. Summary of Technological Characteristics

The Chiron Diagnostics ACS:Centaur AFP Immunoassay is a two-site sandwich Chemiluminescence immunoassay.

7. Performance Data

Sensitivity

The ACS:Centaur AFP Immunoassay measures AFP concentration up to 1000 ng/mL with a minimum detectable concentration of 1.3 ng/mL.

Accuracy

For 498 serum samples in the range of 2.0 to 943.6 ng/mL, the correlation between the ACS:Centaur AFP and the ACS:180 AFP is described by the equation:

$$\text{ACS:Centaur AFP} = 1.05 (\text{ACS:180 AFP}) - 0.3 \text{ ng/mL}$$

Correlation coefficient (r) = 0.99



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 02052-1688

JUL 7 1998

Re: K981592
Trade Name: ACS: Centaur AFP
Regulatory Class: II
Product Code: LOQ
Dated: April 30, 1998
Received: May 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 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.

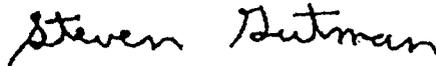
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/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

Company Confidential

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510(k) Number (if known): K981592

Device Name: Chiron Diagnostics ACS:Centaur AFP Immunoassay

Indications for Use:

The ACS:Centaur AFP Immunoassay is for the quantitative determination of alpha-fetoprotein (AFP) in the following:

- * human serum, as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures, using the Chiron Diagnostics ACS:Centaur Automated Chemiluminescence System.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981592

(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)

Premarket Notification - 510(k)
Chiron ACS:Centaur AFP Immunoassay

ACS:Centaur 510(k)

29 June, 1998