

OCT 15 1998

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
Phone: (508) 359-3825
FAX: (508) 359-3885
e-mail: william.pignato@chirondiag.com
Date Summary Prepared: July 28, 1998

2. Device Information

Proprietary Name: ACS:Centaur BR Immunoassay
Common Name: CA 27.29 antigen Immunoassay
Classification Name: Reclassified to Class II, classification
number unknown

3. Predicate Device Information

Name: ACS:180 BR Immunoassay
Manufacturer: Chiron Diagnostics
510(k) Number: K981698

4. Statement of Intended Use

The Chiron Diagnostics ACS:Centaur BR assay is an in vitro diagnostic test for the quantitative serial determination of cancer antigen CA 27.29 in human serum using the Chiron Diagnostics ACS:Centaur™ Automated Chemiluminescence System. The test is intended for use as an aid in monitoring patients previously treated for Stage II or Stage III breast cancer. Serial testing for CA 27.29 in the serum of patients who are clinically free of disease should be used in conjunction with other clinical methods used for the early detection of cancer recurrence. The test is also intended for use as an aid in the management of breast cancer patients with metastatic disease by monitoring the progression or regression of disease in response to treatment.

6. Summary of Technological Characteristics

The Chiron Diagnostics ACS:Centaur BR assay is a fully automated, competitive immunoassay using direct, chemiluminescent technology. The Lite Reagent is composed of a monoclonal mouse antibody specific for CA 27.29, labeled with acridinium ester. The antibody used in the assay, MAb B27.29, binds to a peptide epitope in the tandem repeat region of the MUC-1 gene product. The Solid Phase is composed of purified CA 27.29, which is covalently coupled to paramagnetic particles. After onboard pretreatment, the sample is incubated with both Lite Reagent and Solid Phase simultaneously for 7.5 minutes.

7. Performance Data

Sensitivity

The ACS:Centaur BR assay measures CA 27.29 concentrations up to 450 U/mL with a minimum detectable concentration (analytical sensitivity) of 3.5 U/mL.

Accuracy

For 225 samples in the range of 6.54 to 448.94 U/mL, the relationship of the ACS:Centaur BR assay to the ACS:180 BR assay is described by the following equation:

$$\text{ACS:Centaur BR} = 1.00 (\text{ACS:180 BR}) - 0.94 \text{ U/mL}$$

$$\text{Correlation coefficient (r)} = 0.99$$



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 15 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. William J. Pignato
Director of Regulatory Affairs
Chiron Diagnostics Corporation
63 North Street
Medfield, Massachusetts 02052

Re: K982680
Trade Name: ACS:Centaur BR Immunoassay
Regulatory Class: II
Product Code: MOI
Dated: July 28, 1998
Received: July 31, 1998

Dear Mr. Pignato:

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.

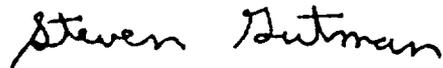
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

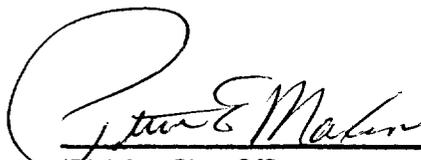
Enclosure

510(k) Number (if known): K982680

Device Name: Chiron Diagnostics ACS:Centaur BR Immunoassay

Indications for Use:

The Chiron Diagnostics ACS:Centaur BR assay is an in vitro diagnostic test for the quantitative serial determination of cancer antigen CA 27.29 in human serum using the Chiron Diagnostics ACS:Centaur™ Automated Chemiluminescence System. The test is intended for use as an aid in monitoring patients previously treated for Stage II or Stage III breast cancer. Serial testing for CA 27.29 in the serum of patients who are clinically free of disease should be used in conjunction with other clinical methods used for the early detection of cancer recurrence. The test is also intended for use as an aid in the management of breast cancer patients with metastatic disease by monitoring the progression or regression of disease in response to treatment.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982680

(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)