

JUL 10 1998

K 981698

SUMMARY OF SAFETY AND EFFECTIVENESS - ACS:180 BR

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 (SMDA 1990) and 21 CFR part 807.92.

Date of Summary Preparation: May 13, 1998

Company Name: Chiron Diagnostics Corporation
333 Coney Street
East Walpole, MA 02032

Company Contact: Nancy A. Hornbaker
Regulatory Affairs
Chiron Diagnostics
Chiron Corporation
4560 Horton Street
Emeryville, CA 94608

Telephone Number: 510.923.2758
FAX: 510.923.3703

Device Name: ACS:180 BR
Automated Chemiluminescence System

Common or Usual Name: Automated Tumor Associated Antigen

Classification: Class II device

Predicate Device: ACS:180 BR

Intended Use and Indications for Use:

The Chiron Diagnostics ACS:180 BR 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:180[®] Automated Chemiluminescence Systems. 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.

Description of the Device:

The Chiron Diagnostics ACS:180 BR assay is a fully automated, competitive, chemiluminescent assay. One reagent, designated Lite Reagent, is composed of a mouse monoclonal 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 breast cancer antigen (CA 27.29) which is covalently coupled to paramagnetic particles (PMP). After onboard pretreatment, the patient serum sample is incubated with both reagents simultaneously for 7.5 minutes.

The ACS: 180 system automatically performs the following steps:

- dispenses sample and Pretreatment Reagent into a cuvette
- dispenses Lite Reagent and Solid Phase and incubates for 7.5 minutes
- separates, aspirates and washes the cuvettes
- dispenses reagents which initiate the chemiluminescent reaction
- reports results

An inverse relationship exists between the concentration of CA27.29 in a sample and the relative light units (RLU) detected by the system.

Comparison to the Predicate Device

The performance of the modified ACS:180 BR assay was compared to that of the predicate device in studies of over 875 specimens from breast cancer patients. These specimens had CA 27.29 levels that spanned the range from 3.68 U/mL to 420 U/mL. The results of the linear regression analysis indicated that the two methods were correlated. The coefficient of determination (r^2) was greater than 0.99, the slope was 1.0408 and the y-intercept was 0.9907 U/mL.

SUMMARY OF SAFETY AND EFFECTIVENESS - (continued)

Comparison of Features

Feature	ACS:180 BR (predicate device)	ACS:180 BR (modified assay)
Specimen type	Serum	Serum
Antigen	CA 27.29	CA 27.29
Antibody	MAb B27.29	MAb B27.29
Antibody Label	Acridinium Ester	Acridinium Ester
Assay Principle	Competitive Immunoassay	Competitive Immunoassay
Detection Method	Chemiluminescence	Chemiluminescence
Calibration	Master Curve Card + 2 calibrators	Master Curve Card + 2 calibrators
Assay Range	3.5 U/mL to 450 U/mL	3.5 U/mL to 450 U/mL
Upper Limit of Normal*	38.6 U/mL	38.6 U/mL
Population to be tested	Patients previously treated for State II and Stage III breast cancer; patients with metastatic disease	Patients previously treated for State II and Stage III breast cancer; patients with metastatic disease
Assay Protocol (Automated)	Dispense 25 μ L sample Dispense 50 μ L Lite Reagent + 250 μ L solid Phase Incubate 7.5 minutes Separate, aspirate, wash cuvettes Dispense 300 μ L reagents which initiate the chemiluminescent reaction Report results	Dispense 25 μ L sample + 22 μ L Pretreatment Reagent Dispense 50 μ L Lite Reagent + 250 μ L solid Phase Incubate 7.5 minutes Separate, aspirate, wash cuvettes Dispense 300 μ L reagents which initiate the chemiluminescent reaction Report results

*This ULN was determined during well-controlled clinical studies. As stated in the product's package insert, each laboratory should determine its own reference range(s).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 10 1998

Ms. Nancy A. Hornbaker
Director Regulatory Affairs
Chiron Corporation
4560 Horton St.
Emeryville, California 94608

Re: K981698
Trade Name: ACS:180 BR
Regulatory Class: II
Product Code: MOI
Dated: May 13, 1998
Received: May 14, 1998

Dear Ms. Hornbaker:

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.

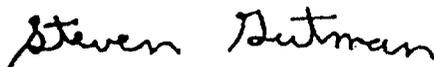
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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

510(k) Number (if known): K981698

Device Name: ACS:180 BR

Indications For Use:

CHIRON DIAGNOSTICS, CHIRON CORPORATION
PREMARKET NOTIFICATION, ACS:180 BR
May 1998

K981698

The Chiron Diagnostics ACS:180 BR 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:180® Automated Chemiluminescence Systems. 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maden

Div: _____
Div: _____ of Calibration Devices *K981698*
510(k) Number: _____

Prescription Use
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1-2-96)