JUN 18 1999

Summary of Safety and Effectiveness

K99/692

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

1. Submitters Information

Contact person:	William J. Pignato Director of Regulatory Affairs
Address:	Chiron Diagnostics Corporation 63 North Street Medfield, MA 02052
Phone: Fax e-mail	(508) 359-3825 (508) 359-3356 william.pignato.b@bayer.com

Date Summary Prepared: April 30, 1999

2. Device Information

Proprietary Name:	Chiron Diagnostics ACS: 180 FT3
Common Name:	Free triiodothyronine test system
Device Classification:	Class II

3. Predicate Device Information

Name:	Chiron Diagnostics ACS: 180 FT3 Immunoassay
Manufacturer:	Chiron Diagnostics Corporation

4. Device Description

Triiodothyronine (3,5,3'-L-triiodothyronine, T_3) is a hormone synthesized and secreted from the thyroid gland, and formed by peripheral deiodination of thyroxine (T_4). T_3 and T_4 are secreted into the circulation in response to thyroid stimulating hormone (TSH) and play an important role in regulating metabolism

In the circulation, 99.7% of T_3 is reversibly bound to transport proteins, primarily thyroxine-binding globulin (TBG) and to a lesser extent albumin and prealbumin. The remaining T_3 does not bind to transport proteins, but is free in the circulation. This unbound fraction of the total T_3 concentration is free triiodothyronine (free T_3, FT_3). Unbound T_3 is metabolically active.

Free T_3 levels correlate with T_3 secretion and metabolism. In hypothyroidism and hyperthyroidism, free T_3 levels parallel changes in total T_3 levels. However, measuring free T_3 is useful when altered levels of total T_3 occur due to changes in T_3 binding proteins, especially TBG. TBG levels remain relatively constant in healthy individuals, but certain conditions such as normal pregnancy and steroid therapy can alter these levels. In these conditions, free T_3 levels are unchanged, while total T_3 levels parallel the changes in TBG.

5. **Statement of Intended Use**

For the quantitative determination of free triiodothyronine (FT_3) in serum using the Chiron Diagnostics ACS:180® Automated Chemiluminescence Systems.

6. **Summary of Technological Characteristics**

The Chiron Diagnostics ACS:180 FT3 assay is a competitive immunoassay using direct, chemiluminescent technology. FT_3 in the sample competes with a T_3 analog, which is covalently coupled to paramagnetic particles in the Solid Phase, for a limited amount of a combination of acridinium ester-labeled monoclonal mouse anti-T_3 antibodies in the Lite Reagent.

The system automatically performs the following steps:

- dispenses 50 µL of sample into a cuvette
- dispenses 100 µL of Lite Reagent and incubates for 5.0 minutes at 37 C
- dispenses 450 µL of Solid Phase and incubates for 2.5 minutes at 37 C
- separates, aspirates, and washes the cuvettes with reagent water
- dispenses 300 µL each of Reagent 1 and Reagent 2 to initiate the chemiluminescent reaction
- reports the results according to the selected option, as described in the system operating instructions or in the online help system

An inverse relationship exists between the amount of FT_3 present in the patient sample and the amount of relative light units (RLUs) detected by the system.

6. **Performance Characteristics**

Expected Results

To determine the ACS:180 FT3 reference range, a study was performed on samples from 594 apparently healthy adult individuals. Ninety-five percent of the FT_3 values for these individuals fell in the range of 2.3 to 4.2 pg/mL (3.5 to 6.5 pmol/L). A study of 185 apparently healthy individuals was performed and found to have a normal range concurrent with the above claim of a normal range spanning 2.3 to 4.2 pg/mL (3.5 to 6.5 pmol/L).

As with all diagnostic assays, each laboratory should determine its own reference range(s) for the diagnostic evaluation of patient results.

Sensitivity and Assay Reportable Range

The ACS:180 FT3 assay measures FT_3 concentrations up to 20 pg/mL (30.8 pmol/L) with a minimum detectable concentration of 0.5 pg/mL (0.8 pmol/L). Analytical sensitivity is defined as the concentration of FT_3 that corresponds to the RLUs that are two standard deviations less than the mean RLUs of multiple replicate determinations of the FT_3 zero standard with multiple lots of reagents and across multiple systems.

Method Comparison

For 359 samples in the range of 0.68 to 17.9 pg/mL (1.05 to 27.6 pmol/L), the relationship between the ACS:180 FT3 assay and an alternate method is described by the equation:
ACS:180 FT3 = 0.93 (alternate method) + 0.319 pg/mL
Correlation coefficient (r) = 0.99

Precision

Three samples were assayed 6 times in each of 12 runs, on 4 systems. The following results were obtained:

Mean (pg/mL)	Mean (pmol/L)	Within-run % CV	Total % CV
2.125	3.272	2.029	2.878
4.592	7.072	1.473	1.649
9.861	15.186	1.359	2.465

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 18 1999

Mr. William J. Pignato
Director of Regulatory Affairs
Chiron Diagnostics Corporation
63 North Street
Medfield, Maine 02052-1688

Re: K991692
Trade Name: Chiron Diagnostics ACS:180® FT3 Assay
Regulatory Class: II
Product Code: CDP
Dated: May 10, 1999
Received: May 18, 1999

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.

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 (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): K 991692

Device Name: Chiron Diagnostics ACS:180 FT3 Assay

Indications for Use:

For the quantitative determination of free triiodothyronine (FT3) in serum using the Chiron Diagnostics ACS:180® Automated Chemiluminescence Systems.

Measurements obtained by this test are used in the diagnosis and treatment of thyroid diseases.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991692

(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