

AUG -5 1999

K992157

Summary of Safety and Effectiveness

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

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Medfield, MA 02052

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Date Summary Prepared: June 22, 1999

2. Device Information

Proprietary Name: Chiron Diagnostics ACS: 180 Ferritin
Common Name: Ferritin Immunological Test System
Device Classification: Class II: 21 CFR 866.5350

3. Predicate Device Information

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

4. Device Description

Ferritin plays a significant role in the absorption, storage, and release of iron. As the storage form of iron, ferritin remains in the body tissues until it is needed for erythropoiesis. When needed, the iron molecules are released from the apoferritin shell and bind to transferrin, the circulating plasma protein that transports iron to the erythropoietic cells.

Although dietary iron is poorly absorbed, the body conserves its iron stores carefully, reabsorbing most of the iron released from the breakdown of red blood cells. As a result, the body normally loses only 1 to 2 mg of iron per day, which is generally restored by the iron absorbed in the small intestine from dietary sources.

Ferritin is found in serum in low concentrations and is directly proportional to the body's iron stores. Serum ferritin concentration, when analyzed with other factors such as serum iron, iron-binding capacity, and tissue iron stores, is valuable in the diagnosis of iron-deficiency anemias, anemias of chronic infection, and conditions such as thalassemia and hemochromatosis that are associated with iron overload. Measurement of serum ferritin is

particularly valuable in distinguishing iron-deficiency anemias caused by low iron stores from those resulting from inadequate iron utilization.

5. Statement of Intended Use

The intended use of Chiron Diagnostics ACS:180 Ferritin Assay is for the quantitative determination of Ferritin in serum or plasma using the Chiron Diagnostics ACS:180® Automated Chemiluminescence Systems; to aid in the diagnosis of iron deficiency anemia and iron overload.

6. Summary of Technological Characteristics

The Chiron Diagnostics ACS:180 Ferritin assay is a two-site sandwich immunoassay using direct, chemiluminometric technology, which uses constant amounts of two anti-ferritin antibodies. The first antibody, in the Lite Reagent, is a polyclonal goat anti-ferritin antibody labeled with acridinium ester. The second antibody, in the Solid Phase, is a monoclonal mouse anti-ferritin antibody, which is covalently coupled to paramagnetic particles.

The ACS:180 system automatically performs the following steps:

- dispenses 25 µL of sample into a cuvette
- dispenses 100 µL of Lite Reagent and 450 µL of Solid Phase and incubates for 7.5 minutes at 37°C
- separates, aspirates, and washes the cuvettes with reagent water⁴
- dispenses 300 µL each of Reagent 1 and Reagent 2 to initiate the chemiluminescent reaction
- reports results according to the selected option, as described in the system operating instructions or in the online help system

A direct relationship exists between the amount of ferritin present in the patient sample and the amount of relative light units (RLUs) detected by the system.

6. Performance Characteristics

Expected Results

In clinical studies, the following values for apparently healthy male and female subjects with normal liver function enzyme tests, bilirubin, and serum iron tests, were determined:

Category	N	Geo. Mean		95th Percentile Range	
		(ng/mL)	(pmol/L)	(ng/mL)	(pmol/L)
Normal Males	142	94	207	22-322	48-708
Normal Females	134	46	101	10-291	22-640

The following values for patients with several diagnosed conditions were determined:

Category	N	Geo. Mean		Total Observed Range	
		(ng/mL)	(pmol/L)	(ng/mL)	(pmol/L)
Iron Deficiency	60	11.6	26	0.68-34.5	1.5-76
Other Anemias	7	610.8	1344	13.0-1390.8	29-3060

Iron Overload	44	1899.6	4178	334.6–8573.0	736–18861
Renal Dialysis	31	312.3	687	31.3–1321.2	68.9–2907
Chronic Liver Disease	34	1967.1	4328	7.9–12826.0	17–28217

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 Ferritin assay measures ferritin concentrations up to 1650 ng/mL (3630 pmol/L) with a minimum detectable concentration of 0.5 ng/mL (1 pmol/L).

Method Comparison

For 276 samples in the range of 3.1 to 1621 ng/mL (6.8 to 3566.2 pmol/L), the relationship between the ACS:180 Ferritin assay and an alternate chemiluminescent method is described by the equation:

$$\text{ACS:180 Ferritin} = 1.01 (\text{alternate chemiluminescent method}) + 1.84 \text{ ng/mL}$$

Correlation coefficient (r) = 1.00

Precision

Four samples were assayed 3 times in 8 assays. The following results were obtained:

Mean (ng/mL)	Mean (pmol/L)	Within-run % CV	Total % CV
13.1	29	2.76	4.98
54.8	121	2.64	6.07
162.7	358	2.73	4.68
359.5	791	3.62	5.08



DEPARTMENT OF HEALTH & HUMAN SERVICES

AUG - 5 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K992157
Trade Name: Chiron Diagnostics ACS: 180 FERRITIN Assay
Regulatory Class: II
Product Code: DBF
Dated: June 22, 1999
Received: June 25, 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.

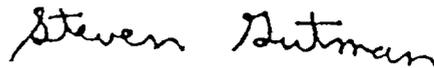
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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

