

K970612

SeaLite Sciences, Inc.

JUN 24 1997

**510(k) SUMMARY**

**I. GENERAL INFORMATION**

**Trade or proprietary name -** SeaLite Sciences, Inc. AquaLite® Ferritin Assay

**Common or usual name -** Bioluminescent immunoassay (BIA)

**Classification name -** FDA has classified ferritin test systems intended for the measurement of ferritin in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia as Class II devices. (21 C.F.R. § 866.5340)

**Submitter's Name and Address:** Cathryn C. Cambria  
Director, Regulatory Affairs and Quality Assurance  
SeaLite Sciences, Inc.  
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Suite 200  
Norcross, GA 30071  
(800) 874-4471, ext. 227

**Submission Date:** February 14, 1997

**Legally Marketed Device To Which Claim Substantial Equivalence:** Chiron Diagnostics ACS:180 Ferritin Assay

**II. INDICATIONS FOR USE**

The AquaLite® Ferritin Bioluminescent Immunoassay (BIA) Kit (or the AquaLite® Ferritin Assay) is an *in vitro* diagnostic product intended for use in clinical laboratories for the quantitative determination of human ferritin in serum and plasma. Ferritin measurements are used in the diagnosis of diseases affecting iron metabolism.

### **III. DEVICE DESCRIPTION**

The AquaLite® Ferritin Bioluminescent Immunoassay Kit uses a mouse monoclonal anti-ferritin antibody that is pre-coated onto polystyrene tubes (solid phase). Samples (serum or plasma), or appropriate calibrators or controls, are pipetted (25  $\mu$ L) into the pre-coated tubes. A mouse monoclonal anti-ferritin antibody covalently linked to AquaLite® (150  $\mu$ L) is then added to the tubes. Ferritin in the sample simultaneously combines with the antibody on the solid phase and conjugate antibody to form an immune complex or "sandwich" bound to the solid phase. Complex formation is complete after a 60-minute incubation period at room temperature on a standard orbital shaker. The tubes are then washed to remove unbound conjugate.

The washed tubes are placed in a luminometer that is capable of reading a triggered, flash-type reaction in 12 x 75 mm tubes. Injection of the calcium trigger buffer causes AquaLite® to oxidize its self-contained luciferin molecule, producing a flash of light, which is measured by the luminometer. The intensity of the light emitted from antibody bound to the tubes is directly proportional to the concentration of the ferritin in the sample. To calculate results, the light intensity (in relative light units, RLU) of the ferritin calibrators is plotted against ferritin concentration (in ng per mL) to yield a calibration curve. This curve is used to relate the light intensity generated from the samples and controls to ferritin concentration in ng/mL.

Note: Samples that generate signals greater than the signal from the highest calibrator are off-scale. These samples must be diluted and re-assayed. Remember to multiply the results from diluted samples by the dilution factor used.

### **IV. SUMMARY OF STUDIES AND TECHNOLOGICAL CHARACTERISTICS**

Studies on the AquaLite® Ferritin Assay were conducted at SeaLite Sciences. The results are summarized below:

#### **Performance Characteristics**

##### **1. Sensitivity**

The sensitivity or detection limit of the AquaLite® Ferritin Assay is 0.03 ng/mL. Sensitivity is determined by adding the mean signal of 20 replicates of the zero level calibrator plus two (2) standard deviations above this mean. The ferritin concentration (ng/mL) associated with this calculated signal is defined as the sensitivity of the assay.

## 2. Specificity

The AquaLite® Ferritin Assay measures intact ferritin. Cross reactivity of the AquaLite® Ferritin assay was determined by measuring the concentration of ferritin in 2 human serum samples spiked with 300 ng/mL liver ferritin. Percent cross-reactivity (%) is reported below:

Endogenous Ferritin (ng/mL)	Ferritin Expected (ng/mL)	Ferritin Observed (ng/mL)	Cross-Reactivity (%)
79	379	323	85
139	439	451	103

## 3. High Dose Hook Effect

No high dose hook effect occurs prior to 10,000 ng/mL ferritin.

## 4. Precision

- (a) **Intra-assay precision.** Two serum commercial controls containing ferritin at the following concentrations were assayed to determine intra-assay precision. (Total N = 20 per concentration level.)

<u>Ferritin Level (ng/mL)</u>	<u>% CV</u>
368.4	8.6
123.9	3.6
40.5	5.4

- (b) **Inter-assay precision.** Commercial controls containing ferritin at the following concentrations were assayed in duplicate repetitively. Ten (10) assays were performed and a new standard curve was generated for each assay. The inter-assay precision observed for the solutions (Total  $n = 2 \times 10 = 20$ ) are shown below.

<u>Ferritin Level (ng/mL)</u>	<u>% CV</u>
50.9	4.5%
121.6	3.7%
363.2	9.3%

5. **Method Comparison**

The AquaLite® Ferritin Assay was used to assay patient samples (N=99) that were previously assayed by a commercially available chemiluminometric immunoassay. A slope of 0.72 with a y-intercept of 15.9 was obtained. The correlation coefficient was 0.98.

6. **Linearity and Nonparallelism**

Three human serum samples containing the levels of endogenous ferritin shown below were diluted as indicated using Calibrator A (0 ng/mL) and assayed in duplicate. All concentrations are in ng/mL.

SAMPLE ID	DILUTION FACTOR	OBSERVED (ng/mL)	FERRITIN EXPECTED (ng/mL)	RECOVERY (%)
A	Undiluted	160.1	---	---
	1:2	77.3	80	96.6
	1:4	47.4	40	118.5
	1:8	23.9	20	119.5
B	Undiluted	294.1	---	---
	1:2	160.9	147	109.5
	1:4	84.4	74	114.1
	1:8	45.1	27	121.9
C	Undiluted	878	---	---
	1:2	383.0	439	87.2
	1:4	189.6	219.5	86.4
	1:8	101.4	109.8	92.3

7. **Spike and Recovery**

Three normal human serum samples were diluted with 120 ng/mL human spleen ferritin (WHO 2nd IS 80/578). The spiked samples were assayed using the AquaLite® Ferritin Assay. All values are in ng/mL.

<u>Sample</u>	<u>Unspiked</u> (ng/mL)	<u>Spike Recovered</u> (ng/mL)	<u>Spiked Expected</u> (ng/mL)	<u>%</u>
1	1260	595	690	86
2	58	90	90	100
3	406	221	263	84

8. **Recovery in Serum and Plasma**

Blood samples from 6 normal subjects were prepared as sera (standard tubes) as well as EDTA plasma. Ferritin was quantified using the AquaLite® Ferritin Assay. Recovered ferritin was compared with the ferritin recovered in serum (standard technique). The data demonstrate that there are no significant differences among serum and EDTA plasma when using the AquaLite® Ferritin Assay.

Sample	Serum (ng/mL)	EDTA (ng/ml)	%
1	63.9	62.0	97
2	44.1	38.7	88
3	62.8	53.6	85
4	109.6	110.9	101
5	105.2	108.8	103
6	63.3	62.6	99

9. **Effect of Common Interferents**

Pooled normal human serum was spiked with preparations of hemoglobin, bilirubin, and triglycerides to the levels shown below. Ferritin was quantified using the AquaLite® Ferritin assay. Recovered ferritin was compared to the ferritin recovered in normal serum. The data demonstrate that the AquaLite® Ferritin assay is not significantly affected by hemoglobin, bilirubin, or triglycerides at the levels tested.

<u>Analyte</u>	<u>Observed</u>	<u>Expected</u>	<u>%</u>
Hgb at 500 mg/dL	113.3	115.6	98
Bilirbn at 20 mg/dL	114.2	115.6	90
Trig at 3000 mg/dL	116.2	128.9	99

V. **POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH**

Caution: Use Universal Precautions. No known test method can offer complete assurance that products derived from human serum are pathogen-free; therefore, handle all materials of human origin as though they were potentially infectious.

Sodium azide is used as a preservative. This preservative may react with metallic plumbing to form explosive metal azides. Flush with large volumes of water when disposing of materials containing sodium azide.

As an *in vitro* diagnostic test, there are not direct adverse effects on the health of a patient from the use of this product. However, failure of the device to perform as indicated, the contamination of reagents, the use of reagents past the labeled expiration dates, the use of improper specimens, or human error during the performance of the test may lead to erroneous results and possible improper patient management.

**VI. CONCLUSIONS DRAWN FROM STUDIES**

The data from the studies conducted demonstrate that the performance of SeaLite Sciences, Inc. AquaLite® Ferritin Assay is similar and substantially equivalent to that of other commercially available assays for ferritin.



Food and Drug Administration  
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Rockville MD 20850

Cathryn C. Cambria  
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SeaLite Sciences, Inc.  
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Norcross, GA 30071

JUN 24 1997

Re: K970612/S001  
Trade Name: SeaLite Sciences, Inc. AquaLite® Ferritin Assay  
Regulatory Class: II  
Product Code: DBF  
Dated: May 08, 1997  
Received: May 12, 1997

Dear Ms. Cambria:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

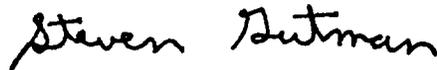
Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

Page 2

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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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

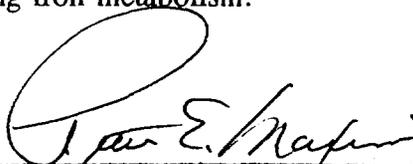
Enclosure

510(k) Number (if known): \_\_\_\_\_

Device Name: AquaLite® Ferritin Bioluminescent Immunoassay (BIA) Kit (or the AquaLite® Ferritin Assay)

**Indications for Use:**

The AquaLite® Ferritin Bioluminescent Immunoassay (BIA) Kit (or AquaLite® Ferritin Assay) is an *in vitro* diagnostic product intended for use in clinical laboratories for the quantitative measurement of ferritin in human serum and plasma. Ferritin measurements are used in the diagnosis of diseases affecting iron metabolism.



\_\_\_\_\_  
**(Division Sign-Off)**  
**Division of Clinical Laboratory Devices**  
**510(k) Number** \_\_\_\_\_

(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)