

K973702

NOV 13 1997

510(k) Summary

**BOEHRINGER
MANNHEIM
CORPORATION**



Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

**1.
Submitter
name,
address,
contact**

Boehringer Mannheim Corporation
4300 Hacienda Drive
Pleasanton, CA 94588-2722
(510) 730 - 8413
Contact Person: Yvette Lloyd

Date Prepared: September 24, 1997

**2.
Device name**

Proprietary name: Elecsys Vitamin B₁₂ Assay

Common name: Electrochemiluminescent immunoassay for the determination of Vitamin B₁₂.

Classification name: System, Test, Vitamin B₁₂

**3.
Predicate
device**

The Boehringer Mannheim Elecsys Vitamin B₁₂ is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed BioRad Quantaphase II B12/Folate Assay (K935286).

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**4.
Device
Description**

Competition principle. Total duration of assay: 18 minutes, 37°C.

•1st incubation (9 minutes): By incubating the sample (15 mL) with the Vitamin B12 pretreatment 1 (15 mL) and pretreatment 2 (15 mL), bound Vitamin B12 is liberated into the serum.

•2nd incubation (9 minutes): By incubating the pretreated sample with the ruthenylated** intrinsic factor (70 mL), an immunocomplex is formed, the amount of which is dependent upon the analyte concentration in the sample.

•3rd incubation (9 minutes): After addition of streptavidin-coated microparticles (30 mL) and Vitamin B12 labeled with biotin (60 mL), the still-vacant sites of the ruthenylated Intrinsic Factor become occupied, with the formation of an ruthenylated Intrinsic Factor-Vitamin B12 biotin complex. The entire complex becomes bound to the solid phase via interaction of biotin and streptavidin.

•The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier (0.4 second read frame).

•Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent bar code.

**Tris(2,2'-bipyridyl)ruthenium(II) complex ($\text{Ru}(\text{bpy})_3^{2+}$)

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**5.
Intended use**

Assay for the in vitro quantitative determination of Vitamin B12 in human serum and plasma.

**6.
Comparison
to predicate
device**

The Boehringer Mannheim Elecsys Vitamin B₁₂ Assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed BioRad Quantaphase II B12/Folate Assay (K935286).

The following table compares the Elecsys Vitamin B₁₂ Assay with the predicate device, BioRad Quantaphase II B12/Folate Assay. Specific data on the performance of the test have been incorporated into the draft labeling in attachment 5. Labeling for the predicate device is provided in attachment 6.

Similarities:

- Intended Use: Assay for the in vitro quantitative determination of Vitamin B₁₂
- Sample type: Serum and plasma
- Assay range: 0- 2000 pg/mL
- Same binding protein: Porcine Intrinsic Factor

Continued on next page



6. Comparison to predicate device cont.

Differences:

Feature	Elecsys Vitamin B ₁₂	Biorad Quantaphase II B ₁₂ /Folate radioassay
Reaction test principle	Electrochemiluminescence	Radiobinding assay using ⁵⁷ Co
Instrument required	Elecsys 2010	Gamma Counter

Performance Characteristics:

Feature	Elecsys Vitamin B ₁₂			BioRad Quantaphase II B ₁₂ /Folate Radioassay			
	Pool 1	Pool 2	Pool 3	I	II	III	IV
Precision	Modified NCCLS (pg/ml):			Within-Run and Total Precision (pg/ml):			
Level	<u>Pool 1</u>	<u>Pool 2</u>	<u>Pool 3</u>	<u>I</u>	<u>II</u>	<u>III</u>	<u>IV</u>
N	60	60	60	40	40	40	40
Mean	203.27	481.02	1499.36	127	273	622	1325
Within run SD	14.11	20.38	41.23	8.9	15.7	51.7	52.8
%CV	6.94	4.24	2.75	4.10	4.1	5.9	4.0
Mean	203.27	481.02	1499.36	127	429	807	1314
Total SD	15.41	21.08	47.78	8.6	29.3	36.2	75.3
%CV	7.58	4.38	3.19	6.8	6.8	4.5	5.7
Level	<u>Level 1</u>	<u>Level 2</u>					
N	60	60					
Mean	1119.49	471.30					
Within run	31.28	25.84					
%CV	2.79	5.48					
Mean	1119.49	471.30					
Total	36.20	26.77					
%CV	3.23	5.68					

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Elecsys Vitamin B ₁₂	BioRad Quantaphase II B ₁₂ /Folate Radioassay
Lower Detection Limit	30 pg/ml	20 pg/ml
Linearity	30 - 2000 pg/ml	20 - 2000 pg/ml
Method Comparison	Vs BioRad Quantaphase II B ₁₂ /Folate Radioassay <u>Least Squares</u> $y = 1.02X + 6.5$ $r = 0.9751$ $N = 346$ <u>Passing Bablock:</u> $y = 1.06X - 9.5$ $r = 0.9751$ $N = 346$	Vs Commercially available radioimmunoassay $y = 1.01x + 44$ $r = 0.933$ $N = 84$

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Elecsys Vitamin B ₁₂	BioRad Quantaphase II B ₁₂ /Folate Radioassay
Interfering substances	No interference at: (within 30 pg/ml at Vitamin B ₁₂ level <300 pg/ml or within ±10% at Vitamin B ₁₂ level > 300 pg/ml.)	No interference at:
Bilirubin	80 mg/dL	20 mg/dL unconjugated 20 mg/dL conjugated
Hemoglobin	1800 mg/dL	500 mg/dL
Lipemia	2500 mg/dL	3000 mg/dL
Rheumatoid Factor	500 IU/mL	N/A
Dysproteinemia	8.8 g/dL	N/A
Biotin	50 pg/ml	N/A
Reference Range Vitamin B ₁₂ , pg/ml	Normal: 243 - 894 Indeterminant: 175 - 244 Deficient:<174	Normal: 130 - 770 Deficient:<204
	% Cross-reactivity	% Cross-reactivity
Cobinamide	0.024	0.1



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Yvette Lloyd
Boehringer Mannheim Corporation
4300 Hacienda Drive
Pléasanton, California 94588-2722

NOV 13 1997

Re: K973702
Trade Name: Elecsys Vitamin B₁₂ Assay
Regulatory Class: II Tier: II
Product Code: CDD
Dated: September 24, 1997
Received: September 26, 1997

Dear Ms. Lloyd:

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.

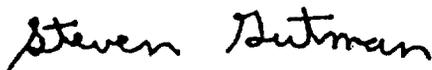
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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): N/A

Device Name: Elecsys Vitamin B₁₂ Assay

Indications For Use:

A vitamin B12 test system is a device intended to measure vitamin B12 in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

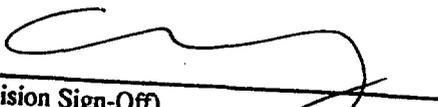
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)


(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number 12973702