K961462

510(k) SUMMARY

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Subject:	Premarket Notification, 510(k) CEDIA® Theophylline Assay application: BM/Hitachi 704 Safety and Effectiveness Summary
Manufacturer:	A Boehringer Mannheim Corporation 2400 Bisso Lane P.O. Box 4117 Concord CA 94524-4117 Phone (510) 674 - 0667 Fax 510 674 1850
Contact:	Betsy Soares-Maddox, Manager of Regulatory Affairs and Quality Assurance
Date:	14 June 1996
Proprietary Name	CEDIA® Theophylline Assay
Common Name	Homogeneous Enzyme Immunoassay for the Determination of Theophylline Levels in Serum and Plasma.
Classification Name	Theophylline Test System
Predicate Device	CEDIA® Theophylline Assay: BM/Hitachi 911
Device Description	CEDIA® Technology The CEDIA® Theophylline Assay is an in-vitro homogeneous enzyme immunoassay used for the measurement of theophylline in serum and plasma. It is based on competitive binding concepts employing theophylline labeled enzymatic fragments (ß-galactosidase) competing with sample theophylline for the theophylline -specific antibody.

Device Description cont. Using recombinant DNA techniques, the ß-galactosidase molecule has been split into two totally inactive polypeptide subunits called enzyme acceptor and enzyme donor. Theophylline has been covalently linked to the enzyme donor in a manner that does not prevent spontaneous reassociation of the subunits to yield active ß-galactosidase enzyme. Theophylline -specific antibody, by binding to the Theophylline derivative on the enzyme donor will inhibit enzyme reassociation, thereby regulating the level of ß-galactosidase formed. The amount of enzyme formed is proportional to the amount of theophylline as monitored by the hydrolysis of the substrate chlorophenol red-ß-D-galactopyranoside (CPRG).

Intended Use The CEDIA Theophylline Assay is a homogeneous enzyme immunoassay for the in vitro assay of theophylline in human serum and plasma. Measurements are used in the diagnosis and treatment of theophylline overdose and in monitoring levels of theophylline to ensure proper therapy.

Statement of Similarities and Differences The following table outlines the similarities and differences between the CEDIA Theophylline Assay on the BM/Hitachi 911 to the BM/Hitachi 704.

Parameter	BM/Hitachi 911	BM/Hitachi 704
Methodology	Homogeneous Enzyme Immunoassay	Homogeneous Enzyme Immunoassay
Intended Use	Quantitative Determination of Theophylline in human serum and plasma	Quantitative Determination of Theophylline in human serum and plasma
Detection Mechanism	Spectrophotometer at 570 nm	Spectrophotometer at 570 nm
Reaction Volumes		
Sample	3 µL	4 µL
R1	130 µL	185 µL
R2	130 µL	170 µL

Statement of Similarities and Differences, cont.

Parameter	BM/Hitachi 911	BM/Hitachi 704
Reagents	Enzyme Acceptor lyophilized with buffer salts, bulking agent, detergent and preservative. Enzyme Donor lyophilized with substrate, stabilizer and preservative. Enzyme Acceptor Reconstitution Buffer with primary antibody, buffer salts, monoclonal anti-Theophylline antibody, stabilizer and preservative. Enzyme Donor Reconstitution Buffer with buffer salts and preservative.	Same
Sensitivity (LDD)	0.8 µg/mL	0.8 µg/mL
Precision	Dose, µg/mL: NCCLS modified	Dose, µg/mL: NCCLS modified
Control Level	Low / Mid / High	Low / Mid / High
Within-Run	5.1 / 15.1 / 29.3	4.7 / 15.1 / 29.2
%CV	3.3 / 1.9 / 1.3	5.5 / 2.8 / 2.1
Total	5.1 / 15.1 / 29.3	4.7 / 15.1 / 29.2
%CV	5.1 / 2.4 / 2.0	6.4 / 3.2 / 2.5

Statement of Similarities and Differences, cont.

Parameter	BM/Hitachi 911	BM/Hitachi 704
Method Comparison Versus:	Fluorescene Polarization Immunoassay	BM/Hitachi 911
Slope	1.01	1.09
Intercept	-0.38	-0.60
Correlation	0.997	0.996

Performance Characteristics

Within-run and total precision were analyzed and the following results were obtained:

Within-run

	Concentration Level		
	Low	Mid	High
Mean, µg/mL	4.7	15.1	29.2
SD, µg/mL	0.26	0.42	0.62
CV, %	5.5	2.8	2.1
N	120	120	120

Total Precision

	Concentration Level		
	Low	Mid	High
Mean, µg/mL	4.7	15.1	29.2
SD, µg/mL	0.30	0.48	0.72
CV, %	6.4	3.2	2.5
N	120	120	120

Method Comparison:

A total of 126 serum samples having theophylline values throughout the assay range were tested with new CEDIA Theophylline Assay on the BM/Hitachi 911 and the BM/Hitachi 704, and yielded the following results:

Number of Observations	Slope	Intercept	Correlation Coefficient
126	1.09	-0.60	0.996

The performance information establishes the basis for substantial equivalence to the predicate device.