

JUN 5 1998

Summary of Safety and Effectiveness

K981312

3rd Generation TSH Method for the Bayer Immuno 1™ System

Listed below is a comparison of the performance of the Bayer Immuno 1™ 3rd Generation TSH (3Gen TSH) method and similar devices granted clearance of substantial equivalence (Bayer Immuno 1 TSH Assay, (Chiron) Ciba-Corning ACS™ TSH-3 Assay and (Roche) Boehringer-Mannheim Elecsys® TSH Assay). The information below was extracted from the Bayer Immuno 1 3rd Generation TSH method sheet and Package Inserts from the other three methods.

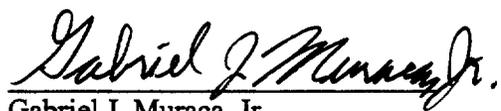
Intended Use

This *in vitro* diagnostic method is intended to quantitatively measure thyroid stimulating hormone (TSH) in human serum or plasma with 3rd generation sensitivity on the Bayer Immuno 1 System. Measurements of TSH, produced by the anterior pituitary, are used in the diagnosis of thyroid or pituitary disorders.

		Bayer Corporation				Ciba-Corning		Boehringer-Mannheim	
		Bayer Immuno 1				ACS:180		Elecsys	
		3GEN TSH		TSH		TSH-3		TSH	
Part Number	Reagents	T01-4038-51		T01-2942-51		570056		1731459	
	Calibrators	T03-4039-01		T03-3568-01		(rgnts and calibs)		1731483	
Expected Values		0.31 - 4.7 µIU/mL		0.47 - 6.9 µIU/mL		0.35 - 5.5 µIU/mL		0.25 - 4.2 µIU/mL	
		<u>mean</u>	<u>% CV</u>	<u>mean</u>	<u>% CV</u>	<u>mean</u>	<u>% CV</u>	<u>mean</u>	<u>% CV</u>
Precision (within-run)		0.008	12.6	0.1	8.0	0.026	10.7	0.084	
	(n = 20 over 10 days)	0.019	4.1	1.3	5.5	0.077	6.5	0.091	2.1
		0.031	3.7	9.0	1.7	0.668	3.9	0.34	8.6
		0.50	4.0	22.5	1.6	4.81	3.3	2.45	1.9
		4.68	2.8			33.503	3.2	3.96	1.8
		29.26	1.4			97.021	4.0	10.67	1.5
		59.03	1.4						
Precision (total)									
	(n = 20 over 10 days)	0.008	12.6	0.1	13.0	0.026	15.8	0.084	5.4
		0.019	5.1	1.3	6.3	0.077	8.4	0.091	3.3
		0.031	3.7	9.0	2.0	0.668	4.1	0.34	8.7
		0.50	4.2	22.5	1.8	4.810	3.5	2.45	2.2
		4.68	3.1			33.503	3.9	3.96	3.6
		29.26	4.1			97.021	5.0	10.67	1.8
		59.03	1.8						
Regression Equation									
	where:	y =	3Gen TSH	y = 0.980x - 0.011		y = 0.928x - 0.021		y = 0.988x - 0.122	
		x =		TSH (2nd Gen)		ACS:180		Elecsys	
		n =		218		203		56	
		r =		0.998		0.996		0.997	
		Sy,x =		1.655		0.676		1.049	
		range =		0.05 - 104.5		0.01 - 68.1		0.01 - 65.3	

Specificity: Cross Reactants Spiked into Normal Human Serum Pools.

Compound	Test Concentration (μ IU/mL)	Crossreactivity (%)
human Chorionic Gonadotropin (hCG)	250,000	< 0.001
Leutinizing Hormone (LH)	2,000	< 0.001
Follicle Stimulating Hormone (FSH)	2,000	< 0.001



Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097


Date



JUN 5 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Gabriel Muraca, Jr.
Manager Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

Re: K981312
3rd Generation TSH Assay for the Bayer Immuno 1™ System
Regulatory Class: I & II
Product Code: JLW, JIS, JJX
Dated: April 7, 1998
Received: April 10, 1998

Dear Mr. Muraca:

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 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.

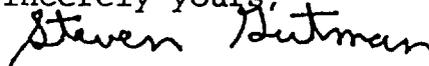
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 (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): K981312

Device Name: **Bayer Immuno 1™ System**
3rd Generation Thyroid Stimulating Hormone (TSH) Assay

Indications For Use:

This *in vitro* diagnostic method is intended to quantitatively measure thyroid stimulating hormone in human serum or plasma on the Bayer Immuno 1 System. Measurements of TSH, with a 3rd Generation sensitivity of <20% total CV at 0.01 μIU/mL to 0.02 μIU/mL (as defined by the American Thyroid Association), are used as an aid in the diagnosis of thyroid or pituitary disorders.

This diagnostic method is not intended for use on any other system.

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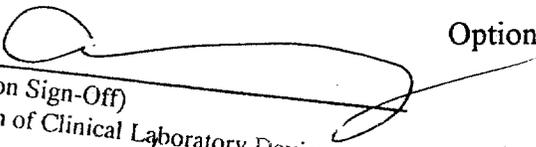
Concurrence of CDRH, Office of Device Evaluation (ODE)

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 K981312