

DEC 7 1998

Summary of Safety and Effectiveness

Bayer Immuno 1™ System Upgraded for Laboratory Automation Capability

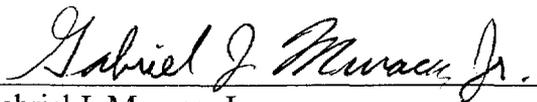
This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. Below is a comparison of performance, using eight representative assays, between the Bayer Immuno 1™ System upgraded for Laboratory Automation capability and the Bayer Immuno 1™ System, already granted clearance of substantial equivalence for these representative and other assays.

Intended Use

The Bayer Immuno 1™ System upgraded for laboratory automation capability will facilitate communication and robotic transfer of samples to and from a Laboratory Automation system. The Laboratory Automation system will coordinate the scheduling, sample identification, and physical transfer of samples.

Device

Bayer Immuno 1™ System Upgraded for Laboratory Automation Capability



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

9/21/98
Date

Part Numbers

CEA:	Reagents: T01-3184-51 Calibrators: T03-3188-01
FSH:	Reagents: T01-3086-51 Calibrators: T03-3148-01
Free T4:	Reagents: T01-3360-51 Calibrators: T03-3401-01
PSA:	Reagents: T01-3450-51 Calibrators: T03-3541-01
T3:	Reagents: T01-2949-01 Calibrators: T03-2872-01
T4:	Reagents: T01-3260-51 Calibrators: T03-3174-01
TSH:	Reagents: T01-2942-51 Calibrators: T03-3568-01
T-Uptake:	Reagents: T01-3036-51 Calibrators: T03-3076-01

Predicate Device

Bayer Immuno 1™ System

Part Numbers

The part numbers are identical to those used for the Bayer Immuno 1™ System upgraded for laboratory automation capability.

1) Precision for Bayer Immuno 1™ System Upgraded for Laboratory Automation Capability:

BAYER IMMUNO 1™ UPGRADED SYSTEM			BAYER IMMUNO 1™ METHOD SHEET	
METHOD	MEAN (UNITS)	TOTAL CV (%)	MEAN (UNITS)	TOTAL CV (%)
CEA	1.54 ng/mL	3.3	2.9 ng/mL	2.3
	13.29 ng/mL	1.2	8.9 ng/mL	2.2
	63.43 ng/mL	1.4	18.2 ng/mL	1.8
FSH	9.4 mIU/mL	1.6	5.5 mIU/mL	3.2
	15.26 mIU/mL	1	12.3 mIU/mL	2.8
	47.51 mIU/mL	0.7	30.3 mIU/mL	2.8
FREE T4	0.83 ng/dL	4.1	0.36 ng/dL	15.4
	1.43 ng/dL	4.3	1.25 ng/dL	6.0
	3.06 ng/dL	4.7	4.35 ng/dL	3.1
PSA	2.89 ng/mL	3.1	0.05 ng/mL	0.007 ng/mL*
	6.9 ng/mL	2.4	0.92 ng/mL	2.9
	26.41 ng/mL	2.4	2.68 ng/mL	3.1
			9.87 ng/mL	2.2
			23.02 ng/mL	3.4
			49.13 ng/mL	2.0
			96.38 ng/mL	2.5
T3	0.66 ng/mL	5.1	0.46 ng/mL	13.3
	1.78 ng/mL	2.4	1.34 ng/mL	6.0
	2.9 ng/mL	2	3.43 ng/mL	3.9
T4	3.31 µg/dL	1.6	4.7 µg/dL	3.6
	7.57 µg/dL	2.2	8.2 µg/dL	2.6
	14.12 µg/dL	1.2	15.7 µg/dL	2.5
TSH	0.55 µIU/mL	6.4	0.1 µIU/mL	13.0
	5.08 µIU/mL	1	1.3 µIU/mL	6.3
	32.73 µIU/mL	1.2	9.0 µIU/mL	2.0
			22.5 µIU/mL	1.8
T-UPTAKE	0.97	3.3	0.71	2.8
	1.03	3.1	1.03	2.6
	1.24	2.2	1.41	2.4

* Standard deviation

2) Correlation:

COMPARISON METHOD	NUMBER OF SAMPLES	REGRESSION EQUATION y =	CORRELATION COEFFICIENT r	STANDARD ERROR S _{y,x}	RANGE OF ANALYTE CONCENTRATION
CEA	360	1.01x - 0.01	0.998	0.116	0.4 - 16.4 ng/mL
FSH	360	0.99x + 0.02	0.999	0.841	0 - 145 mIU/mL
Free T4	355	0.99x + 0.04	0.988	0.042	0.26 - 1.98 ng/dL
PSA	200	1.00x + 0.01	1.000	0.066	0 - 20.3 ng/mL
T3	360	0.99x + 0.02	0.987	0.046	0.48 - 2.16 ng/mL
T4	356	0.98x + 0.07	0.997	0.141	3.7 - 16.4 µg/dL
TSH	360	0.99x + 0.02	1.000	0.108	0.23 - 77 µIU/mL
T-Uptake	358	0.98x + 0.03	0.991	0.019	0.61 - 1.41

y = Bayer Immuno 1™ System upgraded for laboratory automation capability

x = Bayer Immuno 1™ System



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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
BAYER CORPORATION
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: K983345

Trade Name: Bayer Immuno 1™ System Upgraded for Laboratory
Automation Capability

Regulatory Class: II

Product Code: JJE

Dated: September 22, 1998

Received: September 23, 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 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.

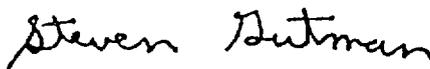
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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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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/dsma/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): K983345

Device Name: **Bayer Immuno 1™ System Upgrade for LAS**

Indications For Use:

The Bayer Immuno 1™ System has been upgraded for Laboratory Automation capability. Software and Hardware will facilitate communication and robotic transfer of samples to and from a Laboratory Automation system. The Laboratory Automation System (LAS) will coordinate the scheduling, sample identification, and physical transfer of samples, as demonstrated for the following representative methods: CEA, FSH, Free T4, PSA, T3, T4, TSH, and T-Uptake.

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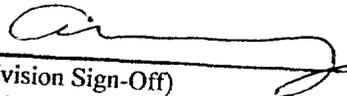
~~Concurrence of CDRH, Office of Device Evaluation (ODE)~~

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

Optional Format 1-2-96)


(Division Sign-Off)
Division of Clinical Laboratory Services
510(k) Number: K983345