

K993549

FEB 1 2000



Summary of Safety & Effectiveness
Beckman Coulter IMMAGE® Immunochemistry System
Low Concentration Immunoglobulin A (IGALC) Reagent
Beckman Coulter™ Cerebrospinal Fluid Protein Calibrator
(CSF CAL)

1.0 **Submitted By:**
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Staff Regulatory Specialist, Product Submissions
Beckman Coulter, Inc.
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2.0 **Date Submitted:**
01 October 1999

3.0 **Device Name(s):**

3.1 **Proprietary Names**

Beckman Coulter IMMAGE® Immunochemistry System
Low Concentration Immunoglobulin A (IGALC) Reagent
Beckman Coulter™ Cerebrospinal Fluid Protein Calibrator
(CSF CAL)

3.2 **Classification Name**

Method, Nephelometric, Immunoglobulins (G, A, M) (21 CFR §866.5510)

4.0 **Predicate Device(s):**

IMMAGE System	Serum Predicate	Manufacturer	Docket Number
IMMAGE System Low Concentration Immunoglobulin A (IGALC) Reagent	IMMAGE Immunochemistry System Immunoglobulin A (IGA) Reagent	Beckman Instruments, Inc.	K963868
Cerebrospinal Fluid Protein Calibrator			
	CSF Predicate	Manufacturer	Docket Number
	N Latex IgA Reagents	Behring Diagnostics, Inc*	K952309

*Westwood, MA 02090

5.0 **Description:**

The IMMAGE® Low Concentration Immunoglobulin A (IGALC) Reagent and Cerebrospinal Fluid Calibrator are designed for optimal performance on the IMMAGE® Immunochemistry Systems. It is intended for the quantitative determination of immunoglobulin A in serum and cerebrospinal fluid.

6.0 **Intended Use:**

The IMMAGE® Immunochemistry System Low Concentration Immunoglobulin A (IGMAC) Reagent, when used in conjunction with Beckman Coulter's IMMAGE® Immunochemistry Systems and Cerebrospinal Fluid Protein Calibrator, is intended for the quantitative determination of human immunoglobulin A in serum and cerebrospinal fluid by rate nephelometry.

7.0 **Comparison to Predicate(s):**

The following tables show similarities and differences between the predicate identified in Section 4.0 of this summary.

SIMILARITIES to the SERUM PREDICATE

IMMAGE System	Aspect/Characteristic	Comments
IMMAGE System IGALC Reagent	Intended use	Same as Predicate device
	Rate nephelometry method	
	Antibody is goat antihuman IgA	
Cerebrospinal Fluid Protein Calibrator	Single level calibrator	

SIMILARITIES to the CSF PREDICATE

IMMAGE System	Aspect/Characteristic	Comments
IMMAGE System IGALC Reagent	Intended use and serum and CSF are acceptable sample types	Same as predicate device
	Reagent storage at 2°C to 8°C	
IMMAGE Cerebrospinal Fluid Protein Calibrator	Protein is of human serum origin	
	Contains azide as a preservative	

DIFFERENCES from the SERUM PREDICATE

IMMAGE System	Aspect/Characteristic	Comments
IMMAGE System IGALC Reagent	Serum or CSF as sample type	Predicate cleared for serum only
IMMAGE Cerebrospinal Fluid Protein Calibrator	CSF CAL Cerebrospinal Fluid Calibrator is a single level, human urine base, azide preserved liquid	Predicate calibrator is a single level, human serum based, azide preserved liquid

DIFFERENCES from the CSF PREDICATE

IMMAGE System	Aspect/Characteristic	Comments
IMMAGE System IGALC Reagent	IMMAGE System IGALC reaction is at a controlled 37°C	Behring N Latex IgA reaction is at room temperature
	Antibody source for IMMAGE IGALC is goat	Antiserum source for Behring N Latex Reagent is rabbit
	IMMAGE Reagent is liquid stable	Behring Reagent is lyophilized
IMMAGE Cerebrospinal Fluid Protein Calibrator	IMMAGE Cerebrospinal Fluid Calibrator is liquid	Behring N IgA Standard is lyophilized

8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison and imprecision experiments.

IMMAGE IGALC Reagent

	Serum IMMAGE IGA	CSF Behring N Latex IgA
N	50	50
Slope	0.973	1.056
Intercept	91.02	0.56
Mean (IGALC) mg/L	2035	6.59
Mean (predicate) mg/L	1999	5.72
Correlation Coefficient	0.984	0.991

Estimated IMMAGE System IGALC Reagent Imprecision (Serum)

PRECISION	SAMPLE	N	MEAN (mg/L)	SD (mg/L)	% CV
Within-Run	Low	80	334	12.7	3.8
	Mid	80	1818	60.3	3.3
	High	80	2922	89.7	3.1
Total	Low	80	334	15.2	4.5
	Mid	80	1818	64.7	3.6
	High	80	2922	103.3	3.5

Estimated IMMAGE System IGALC Reagent Imprecision (CSF)

PRECISION	SAMPLE	N	MEAN (mg/L)	SD (mg/L)	% CV
Within-Run	Low	80	5.06	0.188	3.7
	Mid	80	29.3	0.72	2.5
	High	80	59.8	2.29	3.8
Total	Low	80	5.06	0.208	4.1
	Mid	80	29.3	0.79	2.7
	High	80	59.8	2.70	4.5

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 2000

Mr. Richard T. Ross
Staff Regulatory Specialist
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P.O. Box 8000
Brea, California 92622-8000

Re: K993549
Trade Name: IMAGE® Immunochemistry System
Low Concentration Immunoglobulin A (IGALC) Reagent
Beckman Coulter™ Cerebrospinal Fluid Protein Calibrator (CSF CAL)
Regulatory Class: II
Product Code: CFN
Dated: December 20, 1999
Received: December 21, 1999

Dear Mr. Ross:

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" (21CFR 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

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

K993549

510(k) Number (if known): ~~Not yet assigned~~

Device Name:

**IMAGE® Immunochemistry System
Low Concentration Immunoglobulin A (IGALC) Reagent
Beckman Coulter™ Cerebrospinal Fluid Protein Calibrator (CSF CAL)**

Indications for Use:

The **IMAGE® Immunochemistry System Low Concentration Immunoglobulin A (IGALC) Reagent**, when used in conjunction with Beckman Coulter's **IMAGE® Immunochemistry Systems** and **Cerebrospinal Fluid Protein Calibrator**, is intended for the quantitative determination of human immunoglobulin A in serum and cerebrospinal fluid by rate nephelometry.

Clinical Significance:

The concentration ratio of immunoglobulins in CSF and serum detects increased permeability of the blood-CSF barrier and intrathecal synthesis of immunoglobulins.

The permeability of the blood-CSF barrier to plasma increases due to brain tumor, intracerebral hemorrhage, meningitis, encephalitis, and bacterial infections. The intrathecal synthesis of immunoglobulins is important in the diagnosis of diseases of the Central Nervous Systems (CNS).

**Method, Nephelometric, Immunoglobulins (G, A, M)
(21 CFR §866.5510)**

(b) Classification. Class II.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993549

Prescription Use
(per 21 CFR 801.109)

OR

Over-the-Counter Use
Optional Format 1-2-96