

FEB 1 2000



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

1.0 **Submitted By:**
 Richard T. Ross
 Staff Regulatory Specialist, Product Submissions
 Beckman Coulter, Inc.
 200 South Kraemer Blvd., W-104
 Brea, California 92822-8000
 Telephone: (714) 961-4912 FAX: (714) 961-4123

2.0 **Date Submitted:**
 01 October 1999

3.0 **Device Name(s):**

3.1 **Proprietary Names**

Beckman Coulter IMMAGE® Immunochemistry System
 Low Concentration Immunoglobulin M (IGMLC) 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 M (IGMLC) Reagent	IMMAGE Immunochemistry Systems	Beckman Instruments, Inc.	K963868
Cerebrospinal Fluid Protein Calibrator	Immunoglobulin M (IGM) Reagent		
	CSF Predicate	Manufacturer	Docket Number
	Paragon® Immunofixation Electrophoresis Reagent	Beckman Instruments, Inc.	K823884

5.0 **Description:**

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

6.0 **Intended Use:**

The IMMAGE® Immunochemistry System Low Concentration Immunoglobulin M (IGMLC) 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 M 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

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

SIMILARITIES to the CSF PREDICATE

IMAGE System	Aspect/Characteristic	Comments
IMMAGE System IGMLC Reagent	Intended use	Same as predicate device
	Serum and CSF are acceptable sample types	
	Antibody is goat antihuman IgM	
Cerebrospinal Fluid Protein Calibrator	Single level calibrator	N/A Predicate has no calibrator
	Protein is of human serum origin added to human urine base	

DIFFERENCES from the SERUM PREDICATE

IMAGE System	Aspect/Characteristic	Comments
IMMAGE System IGMLC Reagent	Serum or CSF as sample type	Predicate cleared for serum only
CSF CAL	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

IMAGE System	Aspect/Characteristic	Comments
IMMAGE System IGMLC Reagent	IMMAGE System IGMLC is a rate nephelometric reaction at a controlled 37°C	Predicate is a gel immunofixation electrophoresis at room temperature
	IMMAGE System provides quantitative result based on calibration curve	Qualitative result based on visual comparison to known controls
	Sample may be loaded and/or run neat without pre-analysis concentration	Sample concentration typically required prior to IFE analysis
CSF CAL	Single level calibrator	Predicate has no calibrator

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.

Method Comparisons

Serum Study Results		CSF Study Results		
N	55	N	51	51
Slope	0.977	Test Positive	51	45
Intercept	9.12	Test Negative	0	6
Mean (IGMLC) mg/L	1039	False Positives	6	0
Mean (predicate) mg/L	1054	False Negative	0	0
Correlation Coefficient	0.988	Sensitivity %	100	100
		Specificity %	89.5	100
		% sensitivity = (N/(N + false negative))*100		
		% specificity = (N/(N + false positive))*100		

Estimated IMAGE System IGMLC Reagent Imprecision (Serum)

PRECISION	SAMPLE	N	MEAN (mg/L)	SD (mg/L)	% CV
Within-Run	Low	80	173	5.4	3.2
	Mid	80	869	14.6	1.7
	High	80	1779	31.8	1.8
Total	Low	80	173	6.1	3.5
	Mid	80	869	21.8	2.5
	High	80	1779	35.5	2.0

Estimated IMAGE System IGALC Reagent Imprecision (CSF)

PRECISION	SAMPLE	N	MEAN (mg/L)	SD (mg/L)	% CV
Within-Run	Low	80	0.536	0.0279	5.2
	Mid	80	4.77	0.096	2.0
	High	80	8.61	0.182	2.1
Total	Low	80	0.536	0.0320	6.0
	Mid	80	4.77	0.197	4.1
	High	80	8.61	0.299	3.5

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
Beckman Coulter, Inc.
200 S. Kraemer Boulevard, W-104
P.O. Box 8000
Brea, California 92622-8000

Re: K993547
Trade Name: IMAGE® Immunochemistry System
Low Concentration Immunoglobulin M (IGMLC) 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.

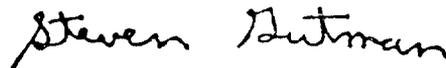
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (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.

Page 2

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 style with a large initial 'S' and 'G'.

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

K993547

page 1 of 1

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

Device Name:

**IMMAGE® Immunochemistry System
Low Concentration Immunoglobulin M (IGMLC) Reagent
Beckman Coulter™ Cerebrospinal Fluid Protein Calibrator (CSF CAL)**

Indications for Use:

The **IMMAGE® Immunochemistry System Low Concentration Immunoglobulin M (IGMLC) 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 M 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.

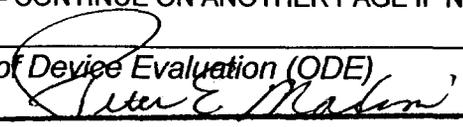
The permeability of the blood-CSF barrier to plasma increases due to brain tumor, intracerebral hemorrhage, meningitis, encephalitis, and bacterial infections. The intrathecal synthesis of immunoglobulins is important in the diagnosis of diseases of the Central Nervous Systems (CNS).

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

(b) Classification. Class II.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

K993547

Prescription Use (per 21 CFR 801.109)

OR

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