K130122

JAN - 7 2014

510(k) SUMMARY

1.0 **Submitted By:**

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2.0 **Date Submitted:**

December 19, 2013

3.0 **Device Name(s):**

3.1 **Proprietary Names**

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

3.2 **Classification Name**

Method, Nephelometric, Immunoglobulins (G, A, M) (21 CFR § 866.5510) [CFN]
Calibrator, multi-analyte mixture (21 CFR § 862.1150) [JIX]

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
Beckman Coulter IMMAGE® Immunochemistry System Low Concentration Immunoglobulin M (IGMLC) Reagent Beckman Coulter Cerebrospinal Fluid Protein Calibrator (CSF CAL)	Beckman Coulter IMMAGE® Immunochemistry System Low Concentration Immunoglobulin M (IGMLC) Reagent Beckman Coulter Cerebrospinal Fluid Protein Calibrator (CSF CAL)	Beckman Coulter, Inc.	K993547

5.0 Description:

The IMMAGE System Low Concentration Immunoglobulin M (IGMLC) Reagent, when used in conjunction with IMMAGE Immunochemistry Systems and Cerebrospinal Fluid Protein Calibrator is intended for the quantitative determination of human Immunoglobulin M in serum and cerebrospinal fluid (CSF) by rate nephelometry.

The IMMAGE Immunochemistry System (cleared under K962294) is a high throughput, random access analyzer that uses rate nephelometry methodology to measure human immunoglobulin M concentration in serum and CSF samples. The IMMAGE Immunochemistry System automatically dilutes and delivers sample to the reaction cuvette along with reagents and other reaction constituents.

During the reaction, particle bound anti-IgM antibody binds to IgM molecules in the sample via an antigen-antibody reaction. This results in the formation of insoluble complexes causing an increase in light scatter. The rate of increase in light scattered from the particles suspended in solution is directly proportional to the concentration of immunoglobulin M in the sample.

The rate nephelometer measures the increase in the intensity of light scattered by particles suspended in a cuvette. The light source for the rate nephelometer is a 670 nm wavelength laser. The detector is placed at a 90° angle from the incident beam to measure light increase. At the end of the reaction, the system mathematically calculates the rate of change of the scatter signal.

6.0 Intended Use:

IMMAGE® Immunochemistry Systems IGMLC Reagent, when used in conjunction with IMMAGE® Immunochemistry Systems and Cerebrospinal Fluid Protein Calibrator, is intended for quantitative determination of immunoglobulin M in human serum or cerebrospinal fluid (CSF) 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.[1,2]
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 System (CNS).[3]

1. European Neurology 1996; 36; 201-205
2. Journal of the Neurological Sciences 184 (2001) 101-122
3. Burtis, C. A., Ashwood, E. R., Tietz, Texbook of Clinical Chemistry, 3rd Edition, W. B. Saunders, Philadelphia, PA (1999).

7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicate identified in Section 4.0 of this summary. Each modification was evaluated against the criteria for a Special 510(k) to insure that the particular change does not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

Similarities			
IMMAGE IGMLC Reagent	Intended Use		
	Reagent formulation		
	Calibrator formulation		
	Technology		
	Methodology		
	Kit configuration		
	Specimen types		
	Stability		
	Reference Interval		
	Precision specification		
	Interferences		
Differences			
IMMAGE IGMLC Reagent	Reagent curve fit optimization	Additional standards added to the low end of the curve.	
	Sensitivity	**Current:** CSF: 0.3 mg/L Serum: 64.8 mg/L	**New:** 0.15 mg/L 32.4 mg/L
	Calibrator traceability	Improved traceability to the international standard, ERM-DA-470(k)-IFCC.	
	Analytical Range	**Current:** CSF 0.3-10 mg/L Serum 64.8-2160 mg/L	**New:** 0.15 – 10 mg/L 32.4 – 2160 mg/L
	Imprecision Value	Included CSF typical imprecision with sample mean concentration between 0.15-0.30 mg/L and updated low end serum sample with mean concentration between 32.4-64.8 mg/L	
	Equivalency	**Current:** CSF: Concordance to IFE method (obsolete) Serum: Comparison to IGM assay **New:** CSF: Comparison to current assay Serum: Comparison to current assay	

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, linearity, and imprecision, and sensitivity experiments.

Method Comparison Study Results

Sample Type	Acceptance Criteria	N	R	Slope	Intercept	Result
CSF	Slope: 1.0 +/- 0.10 Intercept: < 0.075 mg/L R: ≥0.95	80	0.997	0.963	- 0.133	Pass
Serum	Slope: 1.0 +/- 0.10 Intercept: N/A R: ≥ 0.95	80	0.997	1.048	5.70	Pass

Precision Study Results

Sample	N	Mean (mg/L)	Within-Run Precision SD / %CV	Between Run Precision SD / %CV	Between Day Precision SD / %CV	Total Precision SD / %CV
CSF1	80	0.196	0.03 mg/L 16.55%	0 mg/L 0%	0.01 mg/L 4.57%	0.03 mg/L 15.64%
CSF2	80	2.49	0.05 mg/L 2.07%	0.06 mg/L 2.22%	0 mg/L 0%	0.07 mg/L 2.85%
CSF3	80	8.81	0.29 mg/L 3.25%	0.29 mg/L 3.32%	0 mg/L 0%	0.38 mg/L 4.30%
Serum1	80	38.5	3.84 mg/L 9.99%	0.69 mg/L 1.80%	1.46 mg/L 3.81%	4.17 mg/L 10.84%
Serum2	80	1250.1	28.87 mg/L 2.31%	21.33 mg/L 1.71%	0 mg/L 0%	35.59 mg/L 2.85%
Serum3	80	1935.8	55.23 mg/L 2.85%	29.58 mg/L 1.53%	10.23 mg/L 0.53%	63.48 mg/L 3.28%

Conclusion:
As summarized, the modification to the IMMAGE IGMLC Reagent is substantially equivalent to the originally cleared product (K993547). Substantial equivalence has been demonstrated through performance to verify that the device functions as intended and that design specifications have been satisfied.

This 510(k) summary 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

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 7, 2014

BECKMAN COULTER, INC.
C/O MS. AMANDA BROWN
REGULATORY AFFAIRS SPECIALIST
250 S. KRAEMER BLVD M/S E1.2902
BREA, CA 92821

Re: k130122
Trade/Device Name: IMMAGE® Immunochemistry System Low Concentration Immunoglobulin M (IGMLC) Reagent
IMMAGE® Immunochemistry Systems CSF-CAL Cerebrospinal Fluid Protein Calibrator
Regulation Number: 21 CFR § 866.5510
Regulation Name: Immunoglobulins A, G, M, D, and E immunological test system
Regulatory Class: II
Product Code: CFN, JIX
Dated: December 2, 2013
Received: December 3, 2013

Dear Ms. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130122

Device Name
IMMAGE® Immunochemistry System Low Concentration Immunoglobulin M (IGMLC) Reagent

Indications for Use *(Describe)*
IMMAGE® Immunochemistry Systems IGMLC Reagent, when used in conjunction with IMMAGE® Immunochemistry Systems and Cerebrospinal Fluid Protein Calibrator, is intended for quantitative determination of Immunoglobulin M (IGMLC) in human serum or cerebrospinal fluid (CSF) by rate nephelometry.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth A Stafford -S

PSC Publishing Services (301) 443-6740 EF

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130122

Device Name
IMMAGE® Immunochemistry Systems CSF-CAL Cerebrospinal Fluid Protein Calibrator

Indications for Use *(Describe)*
CSF Cal (Cerebrospinal Fluid Protein Calibrator), when used in conjunction with Beckman Coulter Low Concentration Immunoglobulin A (IGALC) and Low Concentration Immunoglobulin M (IGMLC) reagents is intended for use on Immage for the calibration of these reagents.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Elizabeth A. Stafford -S