FEB 13 2006 K 060130

510(k) SUMMARY

1.0 Submitted By:

Annette Hellie
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-110
Brea, CA 92822-8000
Telephone: (714) 993-8767
FAX: (714) 961-4234

2.0 Date Submitted

January 17, 2006

3.0 Device Name(s):

3.1 Proprietary Names
IMMAGE Systems Low Concentration Immunoglobulin A Reagent

3.2 Classification Names
Method, Nephelometric, Imunoglobulins (G, A, M) [865.5510]

4.0 Legally Marketed Device

The IMMAGE Systems Low Concentration Immunoglobulin A Reagent claims substantial equivalence to the IMMAGE Systems Low Concentration Immunoglobulin A Reagent currently in commercial distribution. (FDA 510(k) Number K993549)

5.0 Device 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

IGALC reagent, when used in conjunction with IMMAGE® Immunochemistry Systems and Cerebrospinal Fluid Protein Calibrator, is intended for quantitative determination of Low Concentration Immunoglobulin A (IGALC) in human serum or cerebrospinal fluid (CSF) by rate nephelometry.

7.0 Comparison to the Predicate (Description of the Modification to the Legally Marketed Device)

The IMMAGE Systems Low Concentration Immunoglobulin A reagent serum methods comparison data has been modified to reflect performance of the current reagent production processes. All other performance parameters remain unchanged.

8.0 Summary of Performance Data

Performance data from validation testing supports equivalency.

Section 1: ADMINISTRATIVE INFORMATION

1.0 Submitted By:

Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-110
Brea, CA 92822-8000

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2.0 Sponsor Address/FDA Registration Number

Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-110
Brea, CA 92822-8000
Establishment Registration No. 2050012

3.0 Product Name/Classification Name and Number

Proprietary Names
IMMAGE Systems Low Concentration Immunoglobulin A (IGALC) Reagent

Classification Names
Method, Nephelometric, Imunoglobulins (G, A, M) [866.5510]

4.0 Device Classification

FDA has classified clinical chemistry test systems of this type into Class II

5.0 Section 514 Compliance

This Special 510(k): Device Modification submission is prepared pursuant to the FDA publication: The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Issue Date: March 20, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 13 2006

Beckman Coulter, Inc.
c/o Ms Annette Hellie
Regulatory Affairs
200 South Kraemer Blvd., W-110
Brea, CA 92822

Re: k060130
Trade/Device Name: IMMAGE Systems Low Concentration Immunoglobulin A (IGALC) Reagent
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulins A, G, M, D and E immunological systems
Regulatory Class: Class II
Product Code: CZP
Dated: January 17, 2006
Received: January 18, 2006

Dear Ms. Hellie:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

page 1 of 1

510(k) Number (if known): K060130

Device Name: **IMMAGE® Systems Low Concentration Immunoglobulin A Reagent**

Indications for Use:

INTENDED USE
IGALC reagent, when used in conjunction with IMMAGE® Immunochemistry Systems and Cerebrospinal Fluid Protein Calibrator, is intended for quantitative determination of Low Concentration Immunoglobulin A (IGALC) 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. 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).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Page 1 of _____

Maria Chan
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060130