APR 2 1 2006

510(k) SUMMARY

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.

The assigned 510(k) number is: k060774

Submitter's Name and Address

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318
Telephone: (952) 368-7869
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Contact: Carolyn Anderson

Date Prepared: March 20, 2006

Device Names

Proprietary Name: Folate on the Access® Immunoassay Systems

Common Name: Folate test system

Classification Name: Folic Acid test system

Predicate Device

Access Folate Assay
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

510(k) Numbers: k932887, k943149, k955434

Device Description

The Access Folate reagents, Access Folate Calibrators, Access Folate Lysing Agent, Folate Calibrator S0 and the Access Immunoassay Analyzers (Access, Access 2, Synchron LX®i 725, UniCel DxI™ 800, and UniCel DxC 600i) comprise the Access Immunoassay Systems for the quantitative determination of folic acid levels in human serum, plasma (heparin) and red blood cells.

Intended Use

The Access Folate assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of folic acid levels in human serum, plasma (heparin) and red blood cells using the Access Immunoassay Systems.

Folate levels in both serum and red blood cells are used to assess folate status. The serum folate level is an indicator of recent folate intake. Red blood cell (RBC) folate is the best indicator of long term folate stores. A low RBC folate value can indicate a prolonged folate deficiency.

Comparison of Technological Characteristics

Attribute	Access Folate Assay	Access Folate Assay (modified)
Intended Use	Quantitative determination of folic acid levels in human serum, plasma (heparin) or red blood cells using the Access Immunoassay Systems. Folate levels in both serum and red blood cells are used to assess folate status. The serum folate level is and indicator of recent folate intake. Red blood cell (RBC) folate is the best indicator of long term folate stores. A low RBC folate value can indicate a prolonged folate deficiency.	Same
Methodology	Chemiluminescent immunoassay (two step competitive binding receptor assay)	Same
Product type	Reagent	Same
Sample type	Human serum, plasma (heparin) or red blood cells	Same
Assay components	Reagent pack, calibrators, lysing agent, Folate Calibrator S0	Same
Solid Phase	Goat anti-mouse capture antibody coupled to paramagnetic particles	Same
Conjugate	Folic acid-alkaline phosphatase conjugate	Same
Calibrators	Folate (pteroylglutamic acid) in buffered matrix at levels of 0 and approximately 1.0, 2.5, 5.0, 10.0, and 20.0 ng/mL (2.3, 5.7, 11.3, 22.7, and 45.3 nmol/L)	Same
Reportable Range	Serum folate: 0.5 – 20 ng/mL	Serum folate: 0.5 – 20 ng/mL
Sample Size	55 µL	55 µL

Summary of Technological Characteristics

The device modification consists of a change in buffers for pH adjustment and the re-establishment of the reference interval to reflect the prevalence of folic acid fortification of foods. The modification does not affect the intended use or indications of the device or alter the fundamental scientific technology of the device. The modification does not affect the safety and efficacy of the device.

Conclusion

The modified Access Folate on the Access Immunoassay Systems is substantially equivalent to the Access Folate assay for the quantitative determination folic acid levels in human serum, plasma (heparin) and red blood cells.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Carolyn Anderson
Senior Regulatory Affairs Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

APR 21 2006

Re: k060774
Trade/Device Name: Access Folate on the Access® Immunoassay Systems
Regulation Number: 21 CFR§ 862.1295
Regulation Name: Folic acid test system
Regulatory Class: Class II
Product Code: CGN
Dated: March 20, 2006
Received: March 22, 2006

Dear Ms. Anderson:

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.

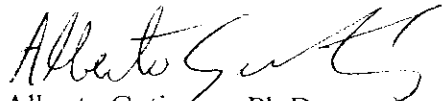
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety 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,



Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: Access Folate on the Access® Immunoassay Systems

Indications For Use:

The Access Folate assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of folic acid levels in human serum, plasma (heparin) and red blood cells using the Access Immunoassay Systems.

Folate levels in both serum and red blood cells are used to assess folate status. The serum folate level is an indicator of recent folate intake. A low RBC folate value can indicate a prolonged folate deficiency.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 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)

Carol Benson

K060774