AUG 19 2011 K111952

Folate Calibrators Safety and Effectiveness 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.

Submitter's Name and Address

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Date Prepared: July 22, 2011

Device Names

Proprietary Name: Access Folate Calibrators
Common Name: Calibrator
Classification Name: Calibrator

Predicate Device

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

510(k) Number: k060774

Device Description

The Access Folate Calibrators are a six level calibrator set intended to calibrate the Access Folate assay for the quantitative determination of folic acid levels in human serum, plasma (heparin) and red blood cells using the Access Immunoassay System. The calibrator set provides calibrators at six levels – zero and approximately 1.2, 3.1, 6.2, 12.4 and 24.8 ng/mL (2.8, 7.0, 14.0, 28.1, and 56.2 nmol/L). The calibrators are contained in 4.0 mL vials. The calibrator vials are intended for storage at -20°C or colder.

Calibration cards are provided with each calibrator kit. Calibration cards contain bar codes that are encrypted with the individual calibrator concentrations for each calibrator level.

Folate Calibrator S0 is intended for use with Access Folate assay to dilute patient samples containing analyte concentrations greater than the analyte specific S5 calibrator. Folate Calibrator S0 is a buffered matrix with human serum albumin (HSA) surfactant, < 0.1% sodium azide, and 0.25% ProClin 300. Contains 0.0 ng/mL (nmol/L) folate.

Intended Use

The Access Folate Calibrators are intended to calibrate the Access Folate assay for the quantitative determination of folic acid levels in human serum, plasma (heparin) and red blood cells using the Access Immunoassay Systems.

Comparison to Predicate

Attribute	Access Folate Calibrator (k060774)	Access Folate Calibrator (restandardized)
Intended Use	The Access Folate Calibrators are intended to calibrate the Access Folate assay for the quantitative determination of folic acid levels in human serum, plasma (heparin) and red blood cells using the Access Immunoassay Systems.	Same
Manufacturer	Beckman Coulter	Same
Storage Temperature after opening	2 - 10°C or colder	Same
Instrumentation / technology	Access Immunoassay Systems	Same
Calibrators Antigen	Folate (pteroylmonoglutamic acid) in buffered matrix	Same
Calibrator Level S0	0 ng/mL 0 nmol/L	0 ng/mL 0 nmol/L
Calibrator Level S1	1.0 ng/mL 2.3 nmol/L	1.2 ng/mL 2.8 nmol/L
Calibrator Level S2	2.5 ng/mL 5.7 nmol/L	3.1 ng/mL 7.0 nmol/L
Calibrator Level S3	5.0 ng/mL 11.3 nmol/L	6.2 ng/mL 14.0 nmol/L
Calibrator Level S4	10.0 ng/mL 22.7 nmol/L	12.4 ng/mL 28.1 nmol/L
Calibrator Level S5	20 ng/mL 45.3 nmol/L	24.8 ng/mL 56.2 nmol/L
Calibrator Range	0 – 20 ng/mL	0 – 25 ng/mL
Self life	12 months	6 months

Conclusion

The Access Folate Calibrators has been demonstrated to be equivalent to the predicate device. Based on the results of the product performance characteristics testing, these calibrators meet product claims specifications. The modifications do not affect the intended use or indications of the device or alter the fundamental scientific technology of the device. The modifications do not affect the safety and efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

AUG 19 2011

Beckman Coulter, Inc.
c/o Kerrie S. Oetter
Senior Regulatory Affairs Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
MS R-275-B
Chaska, MN 55318-1084, USA

Re: k111952
Trade/Device Name: Access Folate Calibrators
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: July 8, 2011
Received: July 11, 2011

Dear Ms. Oetter:

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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, 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 Form

510(k) Number (if known): K111952

Device Name: Access Folate Calibrators on the Access® Immunoassay Systems

Indications For Use:

The Access Folate Calibrators are intended to calibrate the Access Folate assay for the quantitative determination of folic acid levels in human serum, plasma (heparin) and red blood cells using the Access Immunoassay Systems.

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)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111952