August 23, 2023

Beckman Coulter, Inc.
Kuljeet Kaur
Regulatory Affairs Manager
1000 Lake Hazeline Drive
Chaska, Minnesota 55318

Re: K223590
Trade/Device Name: Access Folate Assay
Regulation Number: 21 CFR 862.1295
Regulation Name: Folic Acid Test System
Regulatory Class: Class II
Product Code: CGN
Dated: November 30, 2022
Received: July 27, 2023

Dear Kuljeet Kaur:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-torres -S

Marianela Perez-Torres, Ph.D.
Acting Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223590

Device Name
Access Folate Assay

Indications for Use *(Describe)*
The Access Folate assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of folic acid levels in human serum, lithium heparin plasma, and red blood cells using the Access Immunoassay Systems. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia.
Folate levels in serum, lithium heparin plasma, and red blood cells are used to assess folate status. The serum folate levels is an indicator of recent folate intake. A low RBC folate value can indicate a prolonged folate deficiency.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Access Folate Assay 510(k) Summary

510(k) Number: k223590 Date Prepared: Aug 21, 2023

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitted By:
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Common Name: Folate test system
Trade Name: Access Folate Assay
Classification Name: Folic acid test system
Classification Regulation: 21 CFR 862.1295
Classification Product Code: CGN

Predicate Device:
Device Name: Access Folate Assay
510(k) Numbers: Primary predicate: k060774, Secondary predicate: k111952

Device Description:

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

Intended Use:

The Access Folate assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of folic acid levels in human serum, lithium heparin plasma, and red blood cells using the Access Immunoassay Systems. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia.
Folate levels in serum, lithium heparin plasma, and red blood cells are used to assess folate status. The serum folate levels is an indicator of recent folate intake. A low RBC folate value can indicate a prolonged folate deficiency.

Comparison of Technological Characteristics to the Predicate

System Attribute/Characteristic	Predicate Access Immunoassay Systems (k060774)	Access Folate on DxI 9000 Access Immunoassay Analyzer
Intended Use/Indications for Use	The Access Folate assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of folic acid levels in human serum and plasma (heparin) or red blood cells using the Access Immunoassay Systems.	Same
Analyte Measured	Access Folate	Same
Technology	Competitive binding Immunoassay System	Same
Format	Chemiluminescent	Same
Method	Automated	Same
Calibration	Utilizes a stored calibration curve	Same
Sample Type	Serum, plasma, or red blood cells	Same
Stability	Stable at 2 to 10°C for 14 days after initial use	Same
Instrument	Access 2 Immunoassay System	DxI 9000 Access Immunoassay Analyzer
Substrate	Access Substrate	Lumi-Phos PRO
Measuring Range	1.0 – 24.8 ng/mL	2.0 – 24.8 ng/mL

Comparison of Technological Characteristics to the Predicate

System Attribute/Characteristic	Predicate Access Immunoassay Systems (k111952)	Access Folate on DxI 9000 Access Immunoassay Analyzer
Standardization	World Health Organization (WHO) International Standards	Same

Summary of Studies:

Method Comparison: The results of the within range method comparison study met the acceptance criteria of $R^2 \geq 0.90$ and slope 1.00 ± 0.12 and supports the equivalence of the Access Folate assay on DxI 9000 to the predicate device, the Access Folate assay on Access 2 Instrument. The estimated bias at concentration corresponding to reference limits defined on the predicate system suggest that such values have not changed appreciably on the DxI 9000 analyzer.

N	Concentration Range* (ng/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
123	1.4 - 25	1.04	1.01 - 1.07	0.081	-0.074 - 0.19	0.99

**Range is Access 2 values*

Linearity: A verification study was performed to evaluate the linearity of the Access Folate assay on the DxI 9000 Access Immunoassay Analyzer based on CLSI EP06-Ed2. The results of this study met the acceptance criterion, indicating that the Access Folate assay is linear on the DxI 9000 Immunoassay Analyzer throughout the analytical measuring interval (2.0 - 24.8 ng/mL).

Serum Imprecision: Verification studies were performed to determine the imprecision of the Access Folate assay for serum samples on the DxI 9000 Access Immunoassay Analyzer using a protocol based on CLSI EP-05-A3. The study was run on three DxI 9000 Immunoassay analyzers, three reagent lots, and three calibrator lots. Five (5) serum samples, with varying Folate concentrations, were assayed in duplicate with two runs per day, over 20-22 days. The study met the minimum requirement of 80 replicates per sample on each instrument and reagent lot combination. The within-laboratory (total) % CV was between 2.2% and 4.4% for Folate concentrations > 2.0 ng/mL. The within-laboratory (total) SD was between 0.10 – 0.21 for Folate concentrations ≤ 2.0 ng/mL.
The repeatability (within-run) % CV was between 1.6% and 2.7% for Folate concentrations > 2.0 ng/mL. The repeatability (within-run) SD was between 0.08 – 0.09 for Folate concentrations ≤ 2.0 ng/mL.

Serum Folate (ng/mL)			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	88	1.7	0.09	N/A	0.10	N/A	0.16	N/A	0.21	N/A
Sample 2	88	4.7	0.10	2.1	0.07	1.4	0.17	3.6	0.21	4.4
Sample 3	88	9.2	0.25	2.7	0.00	0.0	0.27	2.9	0.36	3.9
Sample 4	88	16	0.3	2.0	0.2	1.2	0.4	2.7	0.6	3.6
Sample 5	88	21	0.4	2.1	0.3	1.3	0.6	2.7	0.8	3.7

RBC Imprecision: Verification studies were performed to determine the imprecision of the Access Folate assay for hemolysate samples on the DxI 9000 Access Immunoassay Analyzer using a protocol based on CLSI EP-05-A3. The study was run on one DxI 9000 Access Immunoassay Analyzer, one reagent lot, and one calibrator lot. Six whole blood hemolysate samples, with varying Folate concentrations, were tested in the study. The within-laboratory (total) % CV ranged from 1.9% to 4.9%.

Hemolysate Folate Concentration (ng/mL)			Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory	
Sample	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Sample 1	80	5.0	0.21	4.3	0.00	0.004	0.00	0.001	0.21	4.3
Sample 2	80	11	0.3	2.8	0.3	2.8	0.0	0.02	0.5	4.0
Sample 3	80	11	0.5	4.4	0.0	0.02	0.2	2.2	0.5	4.9
Sample 4	80	13	0.2	1.9	0.1	0.5	0.0	0.002	0.3	1.9
Sample 5	80	18	0.4	2.2	0.3	1.8	0.3	1.4	0.6	3.1
Sample 6	80	22	0.4	1.8	0.3	1.2	0.0	0.003	0.5	2.1

LoB/LoD: Verification studies were performed to determine the Limit of Blank (LoB) and Limit of Detection (LoD) for the Access Folate assay on the DxI 9000 Access Immunoassay Analyzer using a protocol based on CLSI EP17-A2. The assay is designed to meet the claimed LoB of 0.80 ng/mL (1.81 nmol/L), LoD of 1.0 ng/mL (2.27 nmol/L).

LoQ: Verification studies were performed to determine the Limit of Quantitation (LoQ) for the Access Folate assay on the DxI 9000 Access Immunoassay Analyzer using a protocol based on CLSI EP17-A2. The LoQ for Access Folate is designed to meet the claimed LoQ of < 2.0 ng/mL (4.53 nmol/L) based on a 20% CV.

Substantial Equivalence Comparison Conclusion

Beckman Coulter's Access Folate Assay on the DxI 9000 Access Immunoassay Analyzer is substantially equivalent to the Access Folate Assay on the Access 2 Immunoassay System as demonstrated through the information and data provided in this submission. The performance testing presented in this submission provides evidence that the device is safe and effective in its intended use.