December 23, 2022

Beckman Coulter, Inc.
Kuljeet Kaur
Regulatory Affairs Manager
1000 Lake Hazeltine Drive
Chaska, MN 55318-1084

Re: K223289
Trade/Device Name: Access Vitamin B12
Regulation Number: 21 CFR 862.1810
Regulation Name: Vitamin B12 test system
Regulatory Class: Class II
Product Code: CDD
Dated: October 25, 2022
Received: October 25, 2022

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,

Paula Caposino -S
Digitally signed by Paula Caposino -S
Date: 2022.12.23 12:57:41 -05'00'

Paula Caposino, Ph.D.
Acting Deputy 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)*
k223289

Device Name
Access Vitamin B12

Indications for Use *(Describe)*

The Access Vitamin B12 assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of vitamin B12 levels in human serum and plasma (heparin) using the Access Immunoassay Systems. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Access Vitamin B12
510(k) Summary

510k Number: k223289 Date Prepared: December 23, 2022

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

Submitted By:
Beckman Coulter, Inc.
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Device Name:
Common Name: Access Vitamin B12 Assay
Trade Name: Access Vitamin B12
Classification Name: Vitamin B12 test system
Classification Product Code: CDD
Regulation: 21 CFR 862.1810

Predicate Device:
Device Name: Access Vitamin B12 Assay
510(k) Number: k955436

Device Description:
The Access Vitamin B12 assay is a competitive binding immunoenzymatic assay. The Access Vitamin B12 reagent kit is in a liquid ready-to-use format designed for optimal performance on Beckman Coulter's immunoassay analyzers. Each reagent kit contains two reagent packs. Other items needed to run the assay include substrate, calibrators, and wash buffer.

Intended Use:

The Access Vitamin B12 assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of vitamin B12 levels in human serum and plasma (heparin) using the Access Immunoassay Systems. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

Comparison of Technological Characteristics to the Predicate

System Attribute/Characteristic	Predicate Access Vitamin B12 on Access Immunoassay System	Access Vitamin B12 on DxI 9000 Access Immunoassay Analyzer
Analyte Measured	Access Vitamin B12	Same
Standardization	USP Reference Material	Same
Intended Use/ Indications for Use	The Access Vitamin B12 assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of vitamin B12 levels in human serum and plasma (heparin) using the Access Immunoassay Systems.	Same
Solid Phase	Paramagnetic particles coated with goat anti-mouse IgG; mouse monoclonal anti-intrinsic factor	Same
Conjugate	Intrinsic factor-alkaline phosphatase	Same
Technology	Two-step competitive	Same
Format	Chemiluminescent	Same
Method	Automated	Same
Calibration	Utilizes a stored calibration curve	Same
Sample Type	Serum or plasma	Same
Reagent Pack formulation and packaging	Access Reagent Pack formulation and packaging.	Same
Stability	Stable at 2 to 10°C for 14 days after initial use	Same
Substrate	Access Substrate	Lumi-Phos PRO Substrate
Measuring Range	50 – 1,500 pg/mL (37 – 1,107 pmol/L)	68 - 1,500 pg/mL (50 - 1,107 pmol/L)
Instrument	Access Immunoassay System	DxI 9000 Access Immunoassay Analyzer

Summary of Studies:

Method Comparison:

A method comparison study was completed to compare the Access Vitamin B12 assay on the DxI 9000 Access Immunoassay Analyzer to the Access Vitamin B12 assay on the Access Immunoassay System using a protocol based on CLSI EP09c-A3. The results of the method comparison study met the acceptance criteria of R2 ≥ 0.90 and slope of 1.00 ± 0.14 and supports the equivalence of the Access Vitamin B12 assay on DxI 9000 Access Immunoassay Analyzer to the Access Vitamin B12 assay on the Access instrument.

N	Concentration Range* (pg/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R^2
122	70 - 1248	1.00	0.96 - 1.02	6.1	-0.16 - 15	0.97

**Range is Access values*

Imprecision: The imprecision study was run on three DxI 9000 Access Immunoassay Analyzers, three reagent lots, and three calibrator lots. Six (6) serum samples, with varying Vitamin B12 concentrations, were assayed in duplicate with two runs per day, over 21 days. The assay was design to meet the requirements of imprecision of SD ≤ 12 pg/mL for values ≤ 100 pg/mL and CV ≤ 12.0 % for values > 100 pg/mL. The observed within-laboratory (total) % CV was between 2.7% and 7.7% for Vitamin B12 concentrations > 100 pg/mL. The within-laboratory (total) SD was between 6 – 9 for Vitamin B12 concentrations ≤ 100 pg/mL. The results from a representative lot are as follows:

Concentration (pg/mL)			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
Sample	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Sample 1	84	71	6	9.0	0	0.0	6	8.5	9	12.4
Sample 2	84	102	5.9	5.8	1.0	1.0	5.1	5.0	7.9	7.7
Sample 3	84	196	5.6	2.9	3.3	1.7	5.5	2.8	8.6	4.4
Sample 4	84	435	9.2	2.1	9.4	2.2	10.3	2.4	16.	3.8
Sample 5	84	944	28.3	3.0	26.	2.8	27.5	2.9	47.	5.0
Sample 6	84	1179	71.9	6.1	0.0	0.0	33.5	2.8	79.	6.7

Linearity: A verification study was performed to determine the linearity of the Access Vitamin B12 assay on the DxI 9000 Access Immunoassay Analyzer based on CLSI EP06-ED2. The results of this study met the acceptance criterion and indicate that the Access Vitamin B12 assay is linear on the DxI 9000 Immunoassay System throughout the analytical measuring interval (68 - 1,500 pg/mL (50 - 1,107 pmol/L).

LoB/LoD: Verification studies were performed to determine the Limit of Blank (LoB) and Limit of Detection (LoD) of the Access Vitamin B12 assay using a protocol based on CLSI EP17-A2. The claimed LoB is 50 pg/mL (37 pmol/L). The assay is designed to meet the requirements for LoD ≤ 68 pg/mL (≤ 50 pmol/L). The results data demonstrate the LoB estimate of the vitamin B12 assay on DxI 9000 is 35 pg/mL (26 pmol/L). The observed LoD of the Vitamin B12 assay on DxI 9000 immunoassay analyzer is 49 pg/mL (36 pmol/L).

LoQ: Verification studies were performed to determine the Limit of Quantitation (LoQ) of the Access Vitamin B12 assay using a protocol based on CLSI EP17- A2 The assay is designed to meet the requirements for LoQ ≤ 68 pg/mL (≤ 50 pmol/L). The results data demonstrate the 20% CV LoQ estimate for the Access Vitamin B12 assay is 42 pg/mL. The results demonstrate the LoQ at 20% within laboratory (total) CV estimate of the Access Vitamin B12 assay to be 68 pg/mL. The maximum observed LoQ estimate for the Access Vitamin B12 assay on the DxI 9000 immunoassay system is less than the reported LoD value (49 pg/mL).

Following the CLSI EP17-A2 recommendation that the LoQ must be greater than or equal to LoD, the LoQ observed value is reported as 49 pg/mL.

Other claims: The claims for the analytical specificity, reference intervals, matrix comparison are being transferred from file k955436.

Substantial Equivalence Comparison Conclusion

Beckman Coulter's Access Vitamin B12 Assay on the DxI 9000 Access Immunoassay Analyzer is substantially equivalent to the Access Vitamin B12 Assay on the Access 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.