October 4, 2019

Beckman Coulter Biomedical GmbH
Amanda Brown
Manager Regulatory Affairs
Sauerbruchstr. 50
Munich, 81377
Germany

Re: K190298
Trade/Device Name: Access Vitamin B12
Access Ferritin
Access Folate
Access TSH (3rd IS)
DxA 5000
DxI 800 Access Immunoassay System
Regulation Number: 21 CFR 862.1810
Regulation Name: Vitamin B12 Test System
Regulatory Class: Class II
Product Code: CDD, JMG, CGN, JLW, JJE
Dated: August 8, 2019
Received: August 21, 2019

Dear Amanda Brown:

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,

Kellie B. Kelm, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k190298

Device Name
DxA 5000, DxI 800 Access Immunoassay System, Access Ferritin Access Folate, Access TSH (3rd IS), Access Vitamin B12

Indications for Use *(Describe)*
The DxA 5000 is a high-speed, modular, automated sample handling system that performs pre-analytical and post-analytical sample processing and storage. The automation system also sorts, routes, and presents sample tubes to analyzers for analysis. The DxA 5000 also consolidates a variety of analytical instruments, such as an Immunoassay analyzer, into a unified workstation on a track system.

The DxI 800 Access Immunoassay System is a microcomputer controlled, random and continuous access analyzer that includes an external computer. This computer stores the system user interface (UI) software and allows the operator to interface with and direct the instrument software. The UniCel DxI 800 System uses enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for the quantitative, semi-quantitative or qualitative determination of various analyte concentrations found in human body fluids. The UniCel DxI 800 System is an in vitro diagnostic device for use in the clinical laboratory.

The Access Ferritin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of ferritin levels in human serum and plasma (heparin) using the Access Immunoassay Systems. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism.

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. Folate levels in serum and plasma (heparin) or 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. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia.

The Access TSH (3rd IS) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of human thyroid-stimulating hormone (thyrotropin, TSH, hTSH) levels in human serum and plasma using the Access Immunoassay Systems. This assay is capable of providing 3rd generation TSH results. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

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.

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1.0 Submitted By:

Amanda Brown, RAC
Manager Regulatory Affairs
Beckman Coulter Biomedical GmbH
Sauerbruchstr. 50
81377 Munich
Germany
Telephone: +49 (0) 89 579589-3611
Email: abrown2@beckman.com

2.0 Date Submitted:

February 8, 2019

3.0 Device Name(s):

3.1 **Proprietary Names**

DxA 5000

DxI 800 Access Immunoassay System
Access Ferritin
Access Folate
Access TSH (3rd IS)
Access Vitamin B12

3.2 **Common Name**

Laboratory Automation System

3.2 **Classification Name**

Name	Regulation Number	Product Code	Device Class	Review Panel
Discrete photometric chemistry analyzer for clinical use	862.2160	JJE	I	Clinical Chemistry
Ferritin immunological test system	866.5340	JMG	II	Clinical Chemistry
Folic acid test system	862.1295	CGN	II	Clinical Chemistry
Thyroid stimulating hormone test system	862.1690	JLW	II	Clinical Chemistry
B12 test system	862.1810	CDD	II	Clinical Chemistry

4.0 Legally Marketed Device

Candidate(s)	Predicate	Manufacturer	Document Number
DxA 5000	Power Processor Sample Processing System	Beckman Coulter, Inc.	K110413

5.0 Device Description

The DxA system is a high throughput automated sample handling system which can perform the pre and post analytical processing of sample tubes. DxA can identify and track samples, perform centrifugation, decapping, delivery of samples to connected analyzers, recapping, storing in either non-refrigerated or refrigerated storage, and sorting to output racks.

The DxA integrates perianalytic (pre and post analysis) functions with analytical instruments (Beckman Coulter, and other manufacturer's) via a track system to provide fully integrated testing solutions.

6.0 Intended Use

The DxA 5000 is a high-speed, modular, automated sample handling system that performs pre-analytical and post-analytical sample processing and storage. The automation system also sorts, routes, and presents sample tubes to analyzers for analysis. The DxA 5000 also consolidates a variety of analytical instruments, such as an Immunoassay analyzer, into a unified workstation on a track system.

7.0 Indications for Use

The DxA 5000 is a high-speed, modular, automated sample handling system that performs pre-analytical and post-analytical sample processing and storage. The automation system also sorts, routes, and presents sample tubes to analyzers for analysis. The DxA 5000 also consolidates a variety of analytical instruments, such as an Immunoassay analyzer, into a unified workstation on a track system.

The UniCel DxI 800 Access Immunoassay System is a microcomputer controlled, random and continuous access analyzer that includes an external computer. This computer stores the system user interface (UI) software and allows the operator to interface with and direct the instrument software. The UniCel DxI 800 System uses enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for the quantitative, semi-quantitative or qualitative determination of various analyte concentrations found in human body fluids. The UniCel DxI 800 System is an in vitro diagnostic device for use in the clinical laboratory.

The Access Ferritin assay is a paramagnetic particle, chemiluminescent assay for the quantitative determination of ferritin levels in human serum and plasma (heparin) using the Access Immunoassay Systems. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism.

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. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia.

The Access TSH (3rd IS) assay is a paramagnetic particle, chemiluminescent assay for the quantitative determination of human thyroidstimulating hormone (thyrotropin, TSH, hTSH) levels in human serum using the Access Immunoassay Systems. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

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

Comparison to the Predicate

Predicate Device Name and 510k information:

Power Processor Sample Processing System (k110413)
Beckman Coulter UniCel® DxI 800 Access® Immunoassay System (k023764)
Beckman Coulter Access® Ferritin assay (k926221)
Beckman Coulter Access® Folate assay (k060774)
Beckman Coulter Access® HYPER sensitive hTSH assay (k042281)
Beckman Coulter Access® Vitamin B12 assay (k955436)

The DxA 5000 has the following similarities to the previously cleared Power Processor Sample Processing System (K110413).

Characteristic	Power Processor	DxA 5000
Intended Use	The basic Power Processor is an automated sample handling system which processes sample tubes from the pre-centrifugation, pre-sorting step to presentation of centrifuged and decapped samples into Generic or Personality Racks for specific instruments. The Power Processor can be configured with optional software and hardware to allow processing of sample tubes on Generic Connection Instruments. The Power Processor performs all pre-analytical sample tube preparation, and then sorts the sample tubes directly to Generic Connection Modules where the samples are pipetted by the Generic Connection instrument for testing. After the samples are pipetted, the tubes can route to other instruments for additional testing or to Outlet Racks.	The DxA 5000 is a high-speed, modular, automated sample handling system that performs pre-analytical and post-analytical sample processing and storage. The automation system also sorts, routes, and presents sample tubes to analyzers for analysis. The DxA 5000 also consolidates a variety of analytical instruments, such as an Immunoassay analyzer, into a unified workstation on a track system.

System Design	Open LAS architecture enables multiple analyzer connections, including 3rd party systems. Scalable, modular configuration.	Same
Fundamental Technology	Centralized operation and monitoring of decentralized equipment.	Same
Sample Transfer Method	Onboard sampling is the physical transfer of the sample tube/rack from the automation track to the analyzer's sample load and identification area. Outboard sampling capability reads the barcode for the analyzer and signals the analyzer's existing LAS communications interface to perform direct track sampling.	Same
Host Communications	The ability to interface with a Laboratory Information System (LIS) device to receive patient identification and test requests via a communications protocol to provide sample tracking via bar code labeling.	The ability to interface with a Laboratory Information System (LIS) device via Remisol to receive patient identification and test requests (based on bar code labeling) and to provide sample tracking via a communications protocol.
Operating Environment	Operating Software Microsoft Windows XP, Computer Console with Single User Interface.	Main Console: Microsoft Windows embedded Standard 7 (64-Bit) with one user interface per system. Module Consoles: Microsoft Windows embedded Standard 7 (32-Bit) with one user interface per module.
Sample Identification	Identification of patient tubes and sample programming using bar codes.	Same
Control panel	Buttons and 2 character display	Touch screen based control on each module console
Racks per Inlet	4 racks that hold 50 tubes each	36 tubes per rack, 4 racks per drawer, 3 drawers

Immunoassay Analyzer Connection	Unicel DxI 800 Access Immunoassay System	Same
Assay Performance	Access Ferritin Assay Access Folate Assay Access HYPERsensitive hTSH Assay Access Vitamin B12 Assay	Same
Throughput	450 tubes per hour (with 2 centrifuges).	Up 1200 tubes per hour
Sample Containers	Primary and secondary Tubes	Same
Aliquotter	Yes	No
Centrifugation	Tube sizes must be all the same.	Can support multiple tube sizes
De-capping	Yes	Same
Sample Identification	Barcode	Same
Sample Storage	Yes	Same
Volume Detection	Yes- (Combination of infrared sensor and pressure sensor)	Yes- (Laser- Liquid Level Detection)

Characteristic	**Power Processor connected to Beckman Coulter UniCel® DxI 800 Access® Immunoassay System**	**DxA 5000 connected to Beckman Coulter UniCel® DxI 800 Access® Immunoassay System**
DxI 800 Indications for Use	The UniCel DxI 800 Access Immunoassay System with laboratory automation connection is a microcomputer-controlled, random and continuous access analyzer that includes an external computer. This computer stores the system user interface (UI) software and allows the operator to interface with and direct the instrument software. The UniCel DxI 800 System uses enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection)	The UniCel DxI 800 Access Immunoassay System is a microcomputer controlled, random and continuous access analyzer that includes an external computer. This computer stores the system user interface (UI) software and allows the operator to interface with and direct the instrument software. The UniCel DxI 800 System uses enzyme immunoassays (utilizing paramagnetic particle solid phase and

	for determination of various analytes, such as Vitamin B12, Ferritin, Folate and hTSH along with other various enzyme immunoassays assays that may be adaptable to the analyzer depending on the reagent used to induce the enzyme immunoassay reaction. The UniCel DxI 800 System is an in vitro diagnostic device for use in the clinical laboratory.	chemiluminescent detection) for the quantitative, semi-quantitative or qualitative determination of various analyte concentrations found in human body fluids. The UniCel DxI 800 System is an in vitro diagnostic device for use in the clinical laboratory.
Main Automation Connection Software	Prep Link software	Remisol software
Sample Identification	Barcode	Same

Characteristic	**Power Processor connected to Beckman Coulter UniCel® DxI 800 Access® Immunoassay System with Ferritin assay**	**DxA 5000 connected to Beckman Coulter UniCel® DxI 800 Access® Immunoassay System with Ferritin assay**
Beckman Coulter Access® Ferritin assay Indications for Use	The Access Ferritin assay is a paramagnetic particle, chemiluminescent assay for the quantitative determination of ferritin levels in human serum and plasma (heparin) using the Access Immunoassay Systems. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism.	The Access Ferritin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of ferritin levels in human serum and plasma (heparin) using the Access Immunoassay Systems.
Sample Identification	Barcode	Same

Characteristic	Power Processor connected to Beckman Coulter UniCel® DxI 800 Access® Immunoassay System with Folate assay	DxA 5000 connected to Beckman Coulter UniCel® DxI 800 Access® Immunoassay System with Folate assay
Beckman Coulter Access® Folate assay 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. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia.	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. Folate levels in serum and plasma (heparin) or 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.
Sample Identification	Barcode	Same

Characteristic	Power Processor connected to Beckman Coulter UniCel® DxI 800 Access® Immunoassay System with hTSH assay	DxA 5000 connected to Beckman Coulter UniCel® DxI 800 Access® Immunoassay System with hTSH assay
Beckman Coulter Access® hTSH assay Indications for Use	The Access HYPER sensitive hTSH assay is a paramagnetic particle, chemiluminescent assay for the quantitative determination of human thyroid-stimulating hormone (thyrotropin, hTSH) levels in human serum using the Access Immunoassay Systems. Measurements of thyroid stimulating hormone produced by	The Access TSH (3rd IS) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of human thyroid-stimulating hormone (thyrotropin, TSH, hTSH) levels in human serum and plasma using the Access Immunoassay Systems. This

	the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.	assay is capable of providing 3rd generation TSH results.
Sample Identification	Barcode	Same

Characteristic	**Power Processor connected to Beckman Coulter UniCel® DxI 800 Access® Immunoassay System with B12 assay**	**DxA 5000 connected to Beckman Coulter UniCel® DxI 800 Access® Immunoassay System with B12 assay**
Beckman Coulter Access® B12 assay Indications for Use	The Access Vitamin B12 assay is a paramagnetic particle, chemiluminescent assay for the quantitative determination of vitamin B12 in human serum and plasma (heparin) using Access Immunoassay Systems. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.	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.
Sample Identification	Barcode	Same

8.0 Summary of Performance Data

The acceptance criteria were met for all method comparisons thereby demonstrating the following:

- Equivalence between the predicate lab automation system Power Processor and the candidate one, DxA 5000 in terms of the DTS barcode identification process.
- Equivalence between the predicate lab automation system Power Processor and the candidate one, DxA 5000 in terms of pre-analytical processing.

A method comparison study was performed utilizing CLSI EP09 for the following assays; TSH (3rd IS) Ferritin, Folate and B12. For all method comparisons, results were within the specifications when the candidate was compared to the predicate.

The above referenced assays are representative of the assay methodologies available for use with the connected system, however performance is not limited to use with these assays.

Performance data from testing shows that all software design, development and verification activities have been completed, and supports a finding of substantial equivalency of DxA 5000 to the Power Processor Sample Processing System.