March 20, 2024

Beckman Coulter, Inc
Kate Oelberg
Senior Staff Quality and Regulatory Affairs
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318

Re: K234052
Trade/Device Name: Access Ferritin
Regulation Number: 21 CFR 866.5340
Regulation Name: Ferritin Immunological Test System
Regulatory Class: Class II
Product Code: JMG
Dated: December 21, 2023
Received: December 21, 2023

Dear Kate Oelberg:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and Hematology 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)*
K234052

Device Name
Access Ferritin

Indications for Use *(Describe)*
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.

Ferritin is used as an aid in the diagnosis of iron deficiency or iron overload.

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.

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.

510(k) Number_____K234052_____

Submitter Name and Address:

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

Primary Contact:

Kate Oelberg, Senior Staff Quality and Regulatory Affairs
Email: kmoelberg@beckman.com
Phone: (612) 431-7315

Alternate Contact:

Kuljeet Kaur, Regulatory Affairs Manager
Email: kkaur@beckman.com
Office Phone: (952) 465-1914

Trade Name: Access Ferritin
Common Name: Ferritin
Classification Regulation: 21 CFR 866.5340
Classification Product Code: JMG

Predicate Device:
Access Ferritin
510(k) Number K926221, k052082

Device Description

The Access Ferritin assay is a sandwich immunoenzymatic assay. The Access Ferritin assay consists of the reagent pack and calibrators. Other items needed to run the assay include substrate and wash buffer. The Access Ferritin assay reagent pack, Access Ferritin assay calibrators, along with the UniCel DxI Wash Buffer II are designed for use with the DxI 9000 Access Immunoassay Analyzer in a clinical laboratory setting.

Intended Use

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. Ferritin is used as an aid in the diagnosis of iron deficiency or iron overload.

Comparison of Technological Characteristics to the Predicate (Assay)

System Attribute/Characteristic	Predicate Access Ferritin assay (k926221/ k052082) run on the Access Immunoassay System	Access Ferritin assay run on the DxI 9000 Access Immunoassay Analyzer Instrument
Intended Use/ Indications for Use	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.	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. Ferritin is used as an aid in the diagnosis of iron deficiency or iron overload.
Analyte Measured	Ferritin	Same
Traceable to	WHO 94/572	Same
Technology	Sandwich Immunoassay	Same
Format	Chemiluminescent	Same
Method	Automated	Same
Calibration	Utilizes a stored calibration curve	Same
Sample Type	Serum/Plasma	Same
Stability	28 days after opening	Same
Reagent Pack formulation and packaging	Access Reagent Pack formulation and packaging.	Same
Reagent Configurations	One Configuration: 100 determinations, 2 packs, 50 tests/pack	Two Configurations: 1) 100 determinations, 2 packs, 50 tests/pack (for predicate and candidate instrument) 2) 200 determinations, 2 packs, 100 tests/pack (for candidate instrument only)
Measuring Range	0.2-1,500 ng/mL Dil-Fer range 1,500-15,000 ng/mL	0.6-1,500 ng/mL Automated dilution: Up to approximately 75,000 ng/mL (µg/L)
Sample Volume	10 uL	5 uL
Instrument	Access Immunoassay system	DxI 9000 Access Immunoassay Analyzer
Substrate	Access Substrate	Lumi-Phos PRO substrate

Standard/Guidance Document Referenced (if applicable):
CLSI EP05-A3: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Third Edition
CLSI EP06-2nd Edition-: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition
CLSI EP09c: Measurement Procedure Comparison and Bias Estimation Using Patient Samples– Third Edition

Summary of Studies:

Method Comparison: A method comparison study was performed to compare the Access Ferritin assay on the DxI 9000 Access Immunoassay Analyzer to the predicate device. A total of one hundred forty-seven (147) samples falling within the measuring range of the Access Ferritin assay were evaluated. The results of the within range method comparison study met the acceptance criteria of R2 ≥ 0.90 and slope 1.00 ± 0.09.

N	Concentration Range* (ng/mL[ug/L])	Slope	Slope 95% CI	Intercept	Intercept 95% CI	R
147	2.3-1471	0.96	0.95-0.97	0.23	-0.34-1.1	0.99

*Range is Access 2 values

Precision: The assay was designed to have within-laboratory imprecision as listed below:
≤ 0.5 ng/mL (µg/L) SD at concentrations ≤ 5 ng/mL (µg/L)
≤ 10.0% CV at concentrations > 5 ng/mL (µg/L)
A study based on CLSI EP05-A317 performed on the DxI 9000 Access Immunoassay Analyzer tested multiple samples in duplicate in 2 runs per day for a minimum of 20 days.

Concentration (ng/mL[ug/L])			Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory (Total)	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
SAMPLE 1	80	1.2	0.2	16.5	0.0	0.0	0.1	5.3	0.2	17.3
SAMPLE 2	80	13	0.4	3.1	0.2	1.3	0.4	3.2	0.6	4.7
SAMPLE 3	80	147	4.5	3.0	2.0	1.4	6.0	4.1	7.7	5.3
SAMPLE 4	80	289	8.6	3.0	0.0	0.0	9.1	3.1	12.5	4.3
SAMPLE 5	80	560	17.2	3.1	10.0	1.8	16.2	2.9	25.7	4.6
SAMPLE 6	80	1276	53.3	4.2	5.8	0.5	42.2	3.3	68.2	5.3

Linearity: A verification study was performed to evaluate the linearity of the Access Ferritin assay on the DxI 9000 Access Immunoassay Analyzer based on CLSI EP06-Ed2. The Access Ferritin assay is linear on the DxI 9000 Access Immunoassay Analyzer throughout the analytical measuring interval of approximately 0.6-1,500 ng/mL

Limit of Blank (LoB): In one study, LoB was tested using a protocol based on CLSI EP17-A2. A total of 75 replicates of native samples were measured using two reagent packs on two DxI 9000 Access Immunoassay Analyzers**.** The claimed LoB for Access Ferritin assay is 0.2 ng/mL on DxI 9000 Access Immunoassay Analyzer.

Limit of Detection (LoD): In one study, LoD was tested using a protocol based on CLSI EP17-A2. Three DxI 9000 Access Immunoassay Analyzers were used in the study design with three reagent lots and one calibrator lot. Five to nine serum samples containing low levels of Ferritin analyte were prepared. Samples were tested over five days with one run per day and nine replicates per run for each pack lot. This resulted in ≥ 40 replicates minimally required for LoD estimation for each sample on each pack lot tested. The claimed LoD estimate for the Access Ferritin assay is 0.4 ng/mL on DxI 9000 Access Immunoassay Analyzer.

Limit of Quantitation (LoQ): In one study, LoQ was tested using a protocol based on CLSI EP17-A2. For estimation of LoQ, eight to twelve serum samples containing low levels of Ferritin analyte were measured. Samples were tested in replicates of nine per run with one run per day and five total days on each pack lot and instrument. A minimum of 40 replicates for each sample on each pack lot was tested.The maximum claimed LoQ ((≤ 20% within-lab CV) determined for the Access Ferritin assay is 0.6 ng/mL on DxI 9000 Access Immunoassay Analyzer).

Other claims: The claims for the analytical specificity, reference intervals, matrix comparison are being transferred from file k926221.

Substantial Equivalence Comparison Conclusion

Beckman Coulter's Access Ferritin assay on the DxI 9000 Access Immunoassay Analyzer is substantially equivalent to Ferritin assay on the Access Immunoassay System (K926221) 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.