April 22, 2024

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

Re: K240182
Trade/Device Name: Access EPO
Regulation Number: 21 CFR 864.7250
Regulation Name: Erythropoietin Assay
Regulatory Class: Class II
Product Code: GGT
Dated: January 22, 2024
Received: January 23, 2024

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,

Min Wu -S

Min Wu, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
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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)*
K240182

Device Name
Access EPO

Indications for Use *(Describe)*
The Access EPO assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of erythropoietin levels in human serum and plasma (heparin) using the Access Immunoassay Systems. This assay is intended as an aid in the diagnosis of anemias and polycythemias.

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 K240182

Submitted By:
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Device Name

Common Name: Access EPO
Trade Name: Access EPO Reagent on DxI 9000 Access Immunoassay Analyzer
Classification Name: Erythropoietin assay
Classification Regulation: [21 CFR 864.7250]

Predicate Device

Device Name: Access EPO
510(k) Numbers: k052223

Device Description

The Access EPO assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of erythropoietin levels in human serum and plasma (heparin) using the Access Immunoassay Systems. This assay is intended as an aid in the diagnosis of anemias and polycythemias.

The Access EPO Calibrators are intended to calibrate the Access EPO assay for the quantitative determination of EPO levels in human serum and plasma (heparin) using the Access Immunoassay Systems.

The Access EPO assay is a two-site immunoenzymatic (“sandwich”) assay. A sample is added to a reaction vessel along with the paramagnetic particles coated with mouse monoclonal anti-EPO, blocking reagent and the alkaline phosphatase conjugate.

After incubation, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of analyte in the sample. Analyte concentration is automatically determined from a stored calibration.

Intended Use

The Access EPO assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of erythropoietin levels in human serum and plasma (heparin) using the Access Immunoassay Systems. This assay is intended as an aid in the diagnosis of anemias and polycythemias.

Comparison of Technological Characteristics to the Predicate

Parameter	Access EPO Assay on Access 2 Immunoassay System (Predicate)	Access EPO Assay on DxI 9000 Access Immunoassay System
Intended use	The Access EPO assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of erythropoietin levels in human serum and plasma (heparin) using the Access Immunoassay Systems. This assay is intended as an aid in the diagnosis of anemias and polycythemias.	Same
Technology	2-site (sandwich) chemiluminescent	Same
Format	Chemiluminescent	Same
Calibration	Utilizes a stored multi-point calibration curve Calibrators are provided at six levels – zero and approximately 5, 25, 125, 375 and 750 mIU/mL	Same
Sample Type	Serum and plasma (heparin)	Same
Measuring Range	0.6-750 mIU/L	Same
Instrument	Access Immunoassay system	DxI 9000 Access Immunoassay Analyzer
Substrate	Access Substrate	Lumi-Phos Pro Substrate

Standard/Guidance Document Referenced (if applicable):

These standards can be copied or found from regulatory submission reports:

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 3rd Edition: Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Third Edition

Summary of Studies

Method Comparison:

A study based on CLSI EP09c, 3rd Edition using Passing-Bablok regression and Pearson's correlation tested 141 native and 11 spiked samples across three Access 2 Immunoassay Systems and three DxI 9000 Access Immunoassay Analyzers.

N	Concentration Range* (mIU/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
152	0.79 – 697	0.99	0.97 – 1.00	-0.040	(-0.19) – 0.22	1.00

*Range is Access 2 values

Imprecision: The assay was designed to have within-laboratory imprecision as listed below:
- ≤ 0.30 mIU/mL SD at concentrations ≤ 3.0 mIU/mL
- ≤ 10.0% CV at concentrations > 3.0 mIU/mL

A study based on CLSI EP05-A3performed on each of four DxI 9000 Access Immunoassay Analyzers tested four native samples and one spiked sample in duplicate in 2 runs per day for 20 days.

Concentration (mIU/L)			Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	80	2.0	0.05	2.3	0.02	1.0	0.06	2.8	0.07	3.8
Sample 2	80	18	0.2	1.2	0.1	0.5	0.5	2.7	0.5	3.0
Sample 3	80	105	2.2	2.2	1.0	1.0	1.4	1.4	2.8	2.7
Sample 4	80	267	4.9	1.8	1.2	0.4	3.8	1.4	6.3	2.4
Sample 5	80	548	9.3	1.7	0.0	0.003	18.1	3.3	20.4	3.7

Linearity: A study based on CLSI EP06-Ed2 performed on the DxI 9000 Access Immunoassay Analyzer determined the assay demonstrated linearity across the measuring interval.

Limit of Blank (LoB): The claimed LoB for Access assay is 0.6 mIU/mL on DxI 9000 Access Immunoassay Analyzer.

Limit of Detection (LoD): The claimed LoD for Access assay is 0.6 mIU/mL on DxI 9000 Access Immunoassay Analyzer.

Limit of Quantitation (LoQ): The claimed LoQ for Access assay is 0.6 mIU/mL on DxI 9000 Access Immunoassay Analyzer.

Substantial Equivalence Comparison Conclusion
Beckman Coulter's Access EPO Assay on the DxI 9000 Access Immunoassay Analyzer is substantially equivalent to the Access EPO 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.