September 22, 2023

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

Re: K223921
Trade/Device Name: Access CEA
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-Associated Antigen Immunological Test System
Regulatory Class: Class II
Product Code: DHX
Dated: August 23, 2023
Received: August 23, 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,

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)*
k223921

Device Name
Access CEA

Indications for Use *(Describe)*

The Access CEA assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Carcinoembryonic Antigen (CEA) levels in human serum, using the Access Immunoassay Systems. CEA measured by the Access Immunoassay Systems is used as an aid in the management of cancer patients in whom changing CEA concentrations have been observed.

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 CEA 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: k223921

Submitter Name and Address:
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Trade Name: Access CEA

Common Name: Carcinoembryonic Antigen Assay

Classification Name: Tumor-associated antigen immunological test system

Classification Regulation: 21 CFR 866.6010

Classification Product Code: DHX

Predicate Device:
Access CEA

510(k) numbers: K991707 and K981985

Device Description

The Access CEA assay is a two-site immunoenzymatic “sandwich” assay using two mouse monoclonal anti-CEA antibodies (MAb) which react with different epitopes of CEA. The Access CEA 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 CEA assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Carcinoembryonic Antigen (CEA) levels in human serum, using the Access Immunoassay Systems. CEA measured by the Access Immunoassay Systems is used as an aid in the management of cancer patients in whom changing CEA concentrations have been observed.

Comparison of Technological Characteristics to the Predicate

Characteristic	Access CEA on Access Immunoassay Analyzer (Predicate)	Access CEA Assay on Dxl 9000 Access Immunoassay Analyzer (Candidate)
Intended use	The Access CEA assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Carcinoembryonic Antigen (CEA) levels in human serum, using the Access Immunoassay Systems. CEA measured by the Access Immunoassay Systems is used as an aid in the management of cancer patients in whom changing CEA concentrations have been observed.	Same
Analyte Measured	Carcinoembryonic Antigen (CEA) in human serum	Same
Technology	One-step sandwich	Same
Format	Chemiluminescent	Same
Method	Automated	Same
Calibrators	Multi-point calibrators containing purified CEA Human in a phosphate buffered BSA matrix with preservatives.	Same

Characteristic	Access CEA on Access Immunoassay Analyzer (Predicate)	Access CEA Assay on DxI 9000 Access Immunoassay Analyzer (Candidate)
Calibration	Utilizes a stored calibration curve	Same
QC Controls	Bi-level controls containing human CEA in a phosphate buffered BSA matrix with preservatives	Same
Sample Type	Serum	Same
Antibody	Monoclonal (mouse) anti-human CEA antibodies	Same
Reagent Stability	Stable at 2 to 10°C for 28 days after initial use	Same
Measuring Range	~0.1 – 1,000 ng/mL	0.2 – 1,000 ng/mL
Substrate	Access Substrate	Lumi-Phos PRO substrate
Instrument	Access 2 Immunoassay system	DxI 9000 Access Immunoassay Analyzer

Summary of Studies

Method Comparison: A method comparison study was performed to compare the Access CEA Assay on DxI 9000 Access Immunoassay Analyzer to the predicate device. A total of one hundred and fifty-three (153) serum samples falling within the measuring range of the Access CEA assay were evaluated. The results of the within range method comparison study met the acceptance criteria of $R^2 \geq 0.90$ and slope 1.00 ± 0.10.

N	Concentration Range* (ng/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
153	0.46 -1071	0.98	0.97 - 0.99	0.058	0.0015 - 0.17	1.00

**Range is Access 2 values*

Imprecision: Verification studies were performed to determine the imprecision of the Access CEA assay on the DxI 9000 Access Immunoassay Analyzer using a protocol based CLSI EP-05-A3 with multiple samples with minimum of three replicates in 2 runs per day for a minimum of 20 days.

Concentration (ng/mL)			Repeatability (Within-run)		Between-run		Between-day		Within- Laboratory (Total)	
Sample	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	126	0.45	0.02	3.5	0.01	1.5	0.01	2.0	0.02	4.3
2	120	5.1	0.10	2.1	0.04	0.8	0.06	1.2	0.13	2.5
3	126	11	0.2	1.9	0.3	2.5	0.2	1.5	0.4	3.5
4	120	89	1.9	2.2	0.8	0.9	1.1	1.3	2.4	2.7
5	120	153	2.8	1.8	1.9	1.3	2.3	1.5	4.1	2.7
6	120	525	18.5	3.5	6.6	1.2	16.0	3.1	25.3	4.8
7	120	865	22.4	2.6	5.3	0.6	38.6	4.5	45.0	5.2

Linearity: The Access CEA assay is linear on the DxI 9000 Access Immunoassay Analyzer throughout the analytical measuring interval of 0.2 - 1,000 ng/mL.

Limit of Blank (LoB): The claimed LoB estimate for the Access CEA assay is 0.09 ng/mL on the DxI 9000 Access Immunoassay Analyzer.

Limit of Detection (LoD): The claimed LoD estimate for the Access CEA assay is 0.1 ng/mL on the DxI 9000 Access Immunoassay Analyzer.

Limit of Quantitation (LoQ): The claimed LoQ determined for Access CEA assay is 0.2 ng/mL on the DxI 9000 Access Immunoassay Analyzer.

Substantial Equivalence Comparison Conclusion

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