December 27, 2022

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

Re: K221990
Trade/Device Name: Access Total βhCG (5th IS)
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (hCG) Test System
Regulatory Class: Class II
Product Code: DHA
Dated: July 5, 2022
Received: July 6, 2022

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 (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,

Marianela Perez-torres -S

Marianela Perez-Torres, Ph.D.
Acting 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)*
k221990

Device Name
ACCESS TOTAL βHCG (5th IS)

Indications for Use *(Describe)*
The Access Total βhCG (5th IS) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total βhCG levels in human serum and plasma using the Access Immunoassay Systems. This assay is intended for use as an aid in the early detection of pregnancy.

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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510 (k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a)(1).

The assigned 510(k) number is k221990.

Submitted By:
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Date Prepared:
July 5, 2022

Device Name:
Common Name: Total βhCG (5th IS) Assay
Trade Name: Access Total βhCG (5th IS)
Classification Name: Human chorionic gonadotropin (HCG) test system
Classification Regulation: [21 CFR 862.1155]
Product Code: DHA

Predicate Device:
The Access Total βhCG (5th IS) Assay/Calibrators claim substantial equivalence to previously cleared Access Total βhCG (5th IS) Assay FDA 510(k) Number K130020 cleared on 10/1/2013.

Device Description:
The Access Total βhCG (5th IS) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total βhCG levels in human serum and plasma using the Access Immunoassay Systems. This assay is intended for use as an aid in the early detection of pregnancy.

Intended Use:

The Access Total βhCG (5 th IS) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total βhCG levels in human serum and plasma using the Access Immunoassay Systems. This assay is intended for use as an aid in the early detection of pregnancy.

Comparison of Technological Characteristics to the Predicate (Assay)

System Attribute/Characteristic	Access Total ββhCG (5th IS) on DxI 9000 Access Immunoassay Analyzer k221990	Predicate Access Total ββhCG (5th IS) on DxI 800 Access Immunoassay System k130020
Intended Use/ Indications for Use	The Access Total βhCG (5th IS) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of human Total βhCG (5th IS) levels in human serum and plasma. This assay is intended for use as an aid in the early detection of pregnancy.	Same
Analyte Measured	Total βhCG	Same
Standardization	WHO 5th International Standard for Chorionic Gonadotropin (NIBSC Code 07/364)	Same
Technology	Two-step sandwich	Same
Format	Chemiluminescent	Same
Method	Automated	Same
Calibration	Utilizes a stored calibration curve	Same
Sample Type	Serum or lithium heparin plasma	Same
Measuring Range	0.6 to approximately 1350 mIU/mL	Same
Stability	Stable at 2 to 10°C for 28 days after initial use	Same
Reagent Pack formulation and packaging	Access Reagent Pack formulation and packaging.	Same
Instrument	DxI 9000 Access Immunoassay Analyzer	UniCel DxI 800 Access Immunoassay System
Substrate	Lumi-Phos PRO substrate	Access Substrate
Reagent Configurations	Two Configurations: 1) 100 determinations, 2	One Configuration: 100 determinations, 2 packs,

System Attribute/Characteristic	Access Total ββhCG (5th IS) on DxI 9000 Access Immunoassay Analyzer k221990	Predicate Access Total ββhCG (5th IS) on DxI 800 Access Immunoassay System k130020
	packs, 50 tests/pack (for predicate and candidate instrument) 2) 200 determinations, 2 packs, 100 tests/pack (for candidate instrument only)	50 tests/pack

Summary of Studies:

Method Comparison: 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 and supports the equivalence of the Access Total βhCG assay on DxI 9000 to the predicate device, the Access Total βhCG assay on Access 2 Instrument. The bias estimate data supports the reference intervals defined on the Access 2 system have not changed appreciably on the DxI 9000 system.

Imprecison: The within-laboratory (total) % CV ranged from 2.5% to 4.7%, for hCG concentrations > 3.9 mIU/mL. The within-laboratory (total) SD ranged from 0.04 to 0.06 for hCG concentrations ≤ 3.9 mIU/mL..

Linearity: This study shows that the acceptance criteria was met for non-linearity within ± 0.39 mIU/mL for values ≤ 3.9 mIU/mL and ± 10.0% for values > 3.9 mIU/mL.

Reproducibility: This study shows that the Access Total βhCG (5th IS) assay meets design input requirements for reproducibility on the DxI 9000 with an SD ≤ 0.51 for values ≤ 3.9 mIU/mL and CV < 13.0% for values > 3.9 mIU/mL.

LoB/LoD: The data demonstrated the LoB estimate of the Total βhCG (5th IS) assay is 0.1 mIU/mL and the LoD is 0.2 mIU/mL.

LoQ: LoQ was determined as the lowest concentration which met the design requirements of 20% CV and recovery of ± 0.1 mIU/mL for three reagent lots when compared to the WHO 5th International Standard for Chorionic Gonadotropin (NIBSC Code 07/364). This study determined the LoQ for Access Total βhCG (5th IS) to be 0.6 mIU/mL (IU/L).

Substantial Equivalence Comparison Conclusion

The information provided in this submission supports a substantial equivalence determination, and therefore 510(k) premarket notification clearance of the Total βhCG (5th IS) assay on DxI 9000 Access Immunoassay Analyzer.