November 10, 2022

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

Re: K221225
Trade/Device Name: Access TSH (3rd IS) Assay, DxI 9000 Access Immunoassay Analyzer
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid Stimulating Hormone Test System
Regulatory Class: Class II
Product Code: JLW, JJE
Dated: August 30, 2022
Received: August 30, 2022

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,

Paula Caposino -S
Digitally signed by Paula Caposino -S
Date: 2022.11.10 10:41:41 -05'00'

Paula Caposino, Ph.D.
Acting Deputy 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k221225

Device Name

Access TSH (3rd IS) Assay, DxI 9000 Access Immunoassay Analyzer

Indications for Use *(Describe)*

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. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders. This assay is capable of providing 3rd generation TSH results.

The DxI 9000 Access Immunoassay Analyzer is an in vitro diagnostic device used for the quantitative, semi-quantitative, or qualitative determination of various analyte concentrations found in human body fluids.

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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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: k221225 **Date Prepared:** November 09, 2022

Submitter Name and address
Beckman Coulter, Inc
1000 Lake Hazeltine Drive
Chaska, MN 55318

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

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

Trade Name: Access TSH (3rd IS) Assay

Common Name: Thyroid stimulating hormone assay

Classification Regulation: 21 CFR 862.1690

Classification Product Code*:* JLW

Trade Name: DxI 9000 Access Immunoassay Analyzer

Common Name: Discrete photometric chemistry analyzer for clinical use

Classification Name: Discrete photometric chemistry analyzer for clinical use

Classification Regulation:21 CFR 862.2160

Classification Product Code: JJE

Predicate Devices:

Access TSH (3rd IS) Assay, 510(k) Number k153651

Access 2 Immunoassay System, 510(k) Number k121214

Device Description

Access TSH (3rd IS) assay is a two-site immunoenzymatic ("sandwich") assay. The Access TSH (3rd IS) 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.

The DxI 9000 Access Immunoassay Analyzer is a fully automated, continuous, random-access sample processing and analysis instrument. The DxI 9000 Access Immunoassay Analyzer 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.

Intended Use

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. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders. This assay is capable of providing 3rd generation TSH results.

The DxI 9000 Access Immunoassay Analyzer is an in vitro diagnostic device used for the quantitative, semi-quantitative, or qualitative determination of various analyte concentrations found in human body fluids.

Comparison Tables:

Comparison of TSH (3rd IS) on DxI 9000 to the predicate (Assay)

System Attribute / Characteristic	TSH (3rd IS)	TSH (3rd IS) K153651
Intended Use	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.	Same
Analyte Measured	Human thyroid-stimulating hormone (thyrotropin, TSH, hTSH)	Same
Standardization	WHO 3rd International Reference Preparation Thyroid Stimulating Hormone, Human (NIBSC Coded 81/565)	Same
Technology	Sandwich immunoassay	Same
Format	Chemiluminescent	Same
Method	Automated	Same
Calibration	Utilizes a stored calibration curve	Same
Sample Type	Serum or plasma	Same
Measuring Range	0.01 – 50.0 µIU/mL	Same

System Attribute / Characteristic	TSH (3rd IS)	TSH (3rd IS) K153651
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 Immunoassay System
Substrate	Lumi-Phos PRO substrate	Access Substrate
Reagent Configurations	Two configurations: 1) 200 determinations, 2 packs, 100 tests/pack (predicate and candidate device) 2) 400 determinations, 2 packs, 200 tests/pack (candidate only)	One Configuration: 200 determinations, 2 packs, 100 tests/pack

Comparison of Technological Characteristics to the Predicate (Instrument)

System Attribute / Characteristic	DxI 9000 Access Immunoassay Analyzer	Predicate Access 2 Immunoassay System K121214
Intended Use	The DxI 9000 Access Immunoassay Analyzer is an in vitro diagnostic device used for the quantitative, semi-quantitative, or qualitative determination of various analyte concentrations found in human body fluids.	The Access 2 system is an *in vitro* diagnostic device used for the quantitative, semi-quantitative, or qualitative determination of various analyte concentrations found in human body fluids.
Signal Source	Photons generated by chemiluminescent substrate reacting with alkaline phosphatase.	Same
Signal Detector	Photomultiplier tube (PMT)	Same
Data Analysis	Internal data reduction methods via microcomputer	Same
Data Output	Digital display and PDF file creation	Digital display and printed alpha-numeric hard copy
Temperature Control	The following modules are temperature controlled: • Reaction build and reaction incubation • Substrate reaction zone • Reagent storage • Sample aliquot storage • Reagent pipettors • Dispense probes	The following modules are temperature controlled: • Reaction incubation • Substrate reaction zone • Reagent storage

Sample Loading Capacity	133 sample containers	60 sample containers
Sample Storage Capacity (on-board)	268 sample vessels	None
Reagent Capacity	50 Access Reagent packs on board	24 Access Reagent packs on board.
Throughput (Maximum tests/hour)	Approximately 450	Approximately 100
Number of Reagent Pipettors	Four	One

Summary of studies:

Method Comparison: A method comparison study was performed to compare the Access TSH (3rd IS) assay on DxI 9000 to the predicate device. A total of one hundred and eleven (111) serum samples falling within the measuring range of the Access TSH (3rd IS) assay were evaluated. The results of the method comparison study met the acceptance criteria of R2 ≥ 0.90 and slope 1.00 ± 0.10.

No. of samples (N)	Access 2 Variable Range Concentration (uIU/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	R2
111	0.01, 47	1.06	1.04, 1.07	-0.019	-0.10, -0.0037	1.00

Imprecision: On the DxI 9000 Access Immunoassay Analyzer, within-laboratory (total) % CV ranged from 2.5% to 4.5%, for TSH concentrations > 0.02 µIU/mL. The within-laboratory (total) SD ranged from 0.0007 to 0.0014 for TSH concentrations ≤ 0.02 mIU/mL.

Concentration (uIU/mL)			Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory (Total)	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	80	0.022	0.0012	5.5	0.0003	1.5	0.0006	2.8	0.0014	6.4
Sample 2	80	0.36	0.009	2.6	0.007	2.0	0.008	2.3	0.014	4.0
Sample 3	80	4.7	0.12	2.5	0.06	1.3	0.07	1.4	0.15	3.2
Sample 5	80	12	0.4	3.8	0.0	0.1	0.2	2.1	0.5	4.3
Sample 4	80	46	1.0	2.1	0.3	0.7	0.8	1.8	1.3	2.8

Reproducibility: The Access TSH (3rd IS) assay is designed to meet the requirements for reproducibility on the DxI 9000 Access Immunoassay Analyzer with an SD ≤ 0.0038 for values ≤ 0.02 uIU/mL and CV < 13.0% for values > 0.02 uIU/mL.

Concentration (uIU/mL)			Repeatability (Within-run)		Between-day		Between - instrument		Reproducibility	
Sample	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Sample 1	75	0.024	0.0006	2.6	0.0004	1.8	0.0006	2.5	0.0010	4.0
Sample 2	75	0.37	0.012	3.3	0.010	2.8	0.000	0.0	0.016	4.3
Sample 3	75	4.8	0.11	2.3	0.14	2.8	0.04	0.7	0.18	3.7
Sample 5	75	12	0.2	2.1	0.2	2.0	0.3	2.4	0.5	3.8
Sample 4	75	46	1.1	2.4	0.5	1.1	1.0	2.1	1.6	3.4

Linearity: The Access Total TSH (3rd IS) assay is linear on the DxI 9000 Immunoassay Analyzer throughout the analytical measuring interval of approximately 0.01 - 50.0 µIU/mL (mIU/L).

Limit of Blank (LoB): The LoB for TSH (3rd IS) is 0.002 µIU/mL on DxI 9000 Access Immunoassay Analyzer.

Limit of Detection (LoD): The LoD estimate for the TSH (3rd IS) assay is 0.003 µIU/mL on DxI 9000 Access Immunoassay Analyzer.

Limit of Quantitation (LoQ): The maximum LoQ determined for the TSH (3rd IS) assay is 0.001 µIU/mL on DxI 9000 Access Immunoassay Analyzer). Following the CLSI EP17-A2 recommendation that the LoQ must be greater than or equal to LoD, the LoQ value is reported as 0.003 µIU/mL to align with LoD.

Substantial Equivalence Comparison Conclusion

Beckman Coulter's TSH (3rd IS) Assay on the DxI 9000 Access Immunoassay Analyzer is substantially equivalent to the Access TSH (3rd IS) 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.