January 19, 2023

Beckman Coulter, Inc.
Kate Oelberg
Regulatory Affairs Manager
1000 Lake Hazeltine Drive
Chaska, MN 55318-1084

Re: K223503
Trade/Device Name: Access 25(OH) Vitamin D Total
Regulation Number: 21 CFR 862.1825
Regulation Name: Vitamin D test system
Regulatory Class: Class II
Product Code: MRG
Dated: November 21, 2022
Received: November 22, 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,

Paula Caposino -S
Digitally signed by Paula Caposino -S
Date: 2023.01.19 15:31:11 -05'00'

Paula Caposino, Ph.D.
Acting Deputy 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)*
k223503

Device Name
Access 25(OH) Vitamin D Total

Indications for Use *(Describe)*
The Access 25(OH) Vitamin D Total assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total 25-hydroxyvitamin D [25(OH) vitamin D] levels in human serum and plasma using the DxI Access Immunoassay Analyzers. Results are to be used as an aid in the assessment of vitamin D sufficiency.

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 SMDA 1990 and 21 CFR 807.92.

510(k) Number K223503 **Date Prepared:** 01/19/2023

Submitter Name and Address:
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Trade Name: Access 25(OH) Vitamin D Total
Common Name: 25(OH) vitamin D
Classification Regulation: 21 CFR 862.1825
Classification Product Code: MRG

Predicate Device:
Access 25(OH) Vitamin D Total
510(k) Number K142373

Device Description

The Access 25(OH) Vitamin D Total assay is a competitive binding immunoenzymatic assay. The Access 25(OH) Vitamin D Total assay consists of the reagent pack and calibrators. Other items needed to run the assay include substrate and wash buffer. The Access 25(OH) Vitamin D Total assay reagent pack, Access 25(OH) Vitamin D Total 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 25(OH) Vitamin D Total assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total 25-hydroxyvitamin D [25(OH) vitamin D] levels in human serum and plasma using the DxI Access Immunoassay Analyzers. Results are to be used as an aid in the assessment of vitamin D sufficiency.

Comparison of Technological Characteristics to the Predicate (Assay)

System Attribute/Characteristic	Predicate Access 25(OH) Vitamin D Total assay (k142373) run on the Access 2 Immunoassay System	Access 25(OH) Vitamin D Total assay run on the DxI 9000 Access Immunoassay Analyzer Instrument
Intended Use/ Indications for Use	The Access 25(OH) Vitamin D Total assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total 25-hydroxyvitamin D [25(OH) vitamin D] levels in human serum and plasma using the Access 2 Immunoassay Systems. Results are to be used as an aid in the assessment of vitamin D sufficiency.	The Access 25(OH) Vitamin D Total assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total 25-hydroxyvitamin D [25(OH) vitamin D] levels in human serum and plasma using the DxI Access Immunoassay Analyzers. Results are to be used as an aid in the assessment of vitamin D sufficiency.
Analyte Measured	25(OH) Vitamin D	Same
Traceable to	NIST-Ghent ID-LC-MS/MS	Same
Technology	Competitive Immunoassay	Same
Format	Chemiluminescent	Same
Method	Automated	Same
Calibration	Utilizes a stored calibration curve	Same
Sample Type	Serum/Li Hep Plasma	Same
Measuring Range	7.0-120 ng/mL (17.5 to 300 nmol/L)	Same
Stability	28 days after opening	Same
Reagent Pack formulation and packaging	Access Reagent Pack formulation and packaging.	Same
Sample Volume	30uL	13uL
Instrument	Access 2 Immunoassay system	DxI 9000 Access Immunoassay Analyzer
Substrate	Access Substrate	Lumi-Phos PRO substrate
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)

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-A3: 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 25(OH) Vitamin D Total assay on the DxI 9000 Access Immunoassay Analyzer to the predicate device. A total of one hundred fifty (150) serum samples falling within the measuring range of the Access 25(OH) Vitamin D Total assay were evaluated. The results of the within range method comparison study met the acceptance criteria of R2 ≥ 0.90 and slope 1.00 ± 0.10.

N	Concentration Range* (ng/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	R
150	7.0 - 120	1.05	0.99 – 1.10	0.94	0.14 – 2.0	0.97

*Range is Access 2 values

Precison: A study based on CLSI EP05-A3 performed on the DxI 9000 Access Immunoassay Analyzer tested multiple serum samples in duplicate in 2 runs per day for a minimum of 20 days. The within-laboratory (total) % CV ranged from 4.3% to 9.0%, for Vitamin D concentrations > 15.0 ng/mL. The within-laboratory (total) SD ranged from 0.09 to 2.2 for Vitamin D concentrations ≤ 15.0 ng/mL.

ng/mL			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	80	7.0	0.8	12.1	0.7	10.6	0.7	9.3	1.3	18.6
Sample 2	80	15.6	0.9	5.5	0.6	3.7	0.9	6.0	1.4	9.0
Sample 3	80	28	1.3	4.4	1.1	4.0	0.9	3.2	1.9	6.8
Sample 4	80	71	1.6	2.3	1.9	2.6	1.8	2.5	3.1	4.3
Sample 5	80	95	2.4	2.5	2.3	2.4	2.8	3.0	4.3	4.5
Sample 6	80	111	3.1	2.8	3.2	2.9	2.1	1.9	4.9	4.5

Linearity: A verification study was performed to evaluate the linearity of the Access 25(OH) Vitamin D Total assay on the DxI 9000 Access Immunoassay Analyzer based on CLSI EP06-Ed2. The Access 25(OH) Vitamin D Total assay is linear on the DxI 9000 Access Immunoassay Analyzer throughout the analytical measuring interval of approximately 7.0-120 ng/mL

Limit of Blank (LoB): In one study, LoB was tested using a protocol based on CLSI EP17-A2. A total of 120 replicates of a zero analyte sample (Access 25(OH) Vitamin D Total Calibrator S0) were measured using multiple reagent packs on multiple DxI 9000 Access Immunoassay Analyzers**.** The LoB for Access 25(OH) Vitamin D Total assay is 2.5 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. Eight to eleven serum samples containing low levels of Vitamin D 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 LoD estimate for the Access 25(OH) Vitamin D Total assay is 4.5 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, 10-13 serum samples containing low levels of Vitamin D 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 LoQ (≤ 20% within-lab CV) determined for the Access 25(OH) Vitamin D Total assay is 7.0 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 K142373.

Substantial Equivalence Comparison Conclusion

Beckman Coulter's Access 25(OH) Vitamin D Total assay on the DxI 9000 Access Immunoassay Analyzer is substantially equivalent to Access 25(OH) Vitamin D Total assay on the Access 2 Immunoassay System (K142373) 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.