March 1, 2024

Beckman Coulter, Inc.
Neha Desai
Staff Quality and Regulatory Affairs
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318

Re: K232791
Trade/Device Name: Access Intact PTH
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid hormone test system
Regulatory Class: Class II
Product Code: CEW
Dated: January 22, 2024
Received: January 22, 2024

Dear Neha Desai:

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,

Paula V. Caposino -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K232791

Device Name

Access Intact PTH

Indications for Use *(Describe)*

The Access Intact PTH assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of intact parathyroid hormone (parathyrin, PTH) levels in human serum and plasma using the Access Immunoassay Systems.
It is indicated to aid in the differential diagnosis of hyperparathyroidism, hypoparathyroidism, or hypercalcemia of malignancy and can be used intraoperatively. Assay results should be used in conjunction with other clinical data to assist the clinician in making individual patient management decisions.

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 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 K232791

Submitter Name and Address:
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Trade Name: Access Intact PTH
Common Name: Parathyroid Hormone Test
Classification Regulation: 21 CFR 862.1545
Classification Product Code: CEW

Predicate Device:
Access Intact PTH
510(k) Number K061190

Device Description

The Access Intact PTH assay is a sandwich immunoenzymatic assay. The Access Intact PTH assay consists of the reagent pack and calibrators. Other items needed to run the assay include substrate and wash buffers. The Access intact PTH assay reagent pack, Access intact PTH assay calibrators, along with the Access wash buffer and substrate are designed for use on the DxI 9000 Access Immunoassay Analyzers in a clinical laboratory setting.

Intended Use

The Access Intact PTH assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of intact parathyroid hormone (parathyrin, PTH) levels in human serum and plasma using the Access Immunoassay Systems. It is indicated to aid in the differential diagnosis of hyperparathyroidism, hypoparathyroidism, or hypercalcemia of malignancy and can be used intraoperatively. Assay results should be used in conjunction with other clinical data to assist the clinician in making individual patient management decisions.

Comparison of Technological Characteristics to the Predicate (Assay)

System Attribute/Characteristic	Predicate Access Intact PTH on Access 2 Immunoassay System	Access Intact PTH on DxI 9000 Access Immunoassay Analyzer
Intended Use/ Indications for Use	The Access Intact PTH assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of intact parathyroid hormone (parathyrin, PTH) levels in human serum and plasma using the Access Immunoassay Systems. It is indicated to aid in the differential diagnosis of hyperparathyroidism, hypoparathyroidism, or hypercalcemia of malignancy and can be used intraoperatively. Assay results should be used in conjunction with other clinical data to assist the clinician in making individual patient management decisions.	Same
Assay Principle	The Access Intact PTH assay is a two-site immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel, along with a monoclonal anti-PTH antibody conjugated to alkaline phosphatase, TRIS buffered saline with proteins and paramagnetic particles coated with a goat polyclonal anti-PTH antibody.	Same
Solid Support	Paramagnetic Particles	Same
Calibration	Six levels (10, 60, 300, 1,500 and 3,500 pg/mL) of synthetic PTH antigen in a buffered protein solution with preservatives	Same
Sample Type	Serum or Plasma (Heparin and EDTA)	Same
Measuring Range	1 – 3,500 pg/mL	1.7 – 3,500 pg/mL
Stability	Stable at 2 to 10°C for 28 days	Same

System Attribute/Characteristic	Predicate Access Intact PTH on Access 2 Immunoassay System	Access Intact PTH on DxI 9000 Access Immunoassay Analyzer
	after initial use	
Instrument	Access 2 Immunoassay system	DxI 9000 Access Immunoassay Analyzer
Substrate	Access Substrate	Lumi-Phos PRO substrate

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: Measurement Procedure Comparison and Bias Estimation Using Patient Samples– Third Edition

Summary of Studies:

Imprecision:

The Routine Mode assay and Intraoperative Mode assay were designed to have within-laboratory imprecision as listed below:

- ≤ 0.96 pg/mL (0.10 pmol/L) SD at concentrations ≤ 12 pg/mL (1.3 pmol/L)
- ≤ 8.0% CV at concentrations > 12 pg/mL (1.3 pmol/L)

A study based on CLSI EP05-A3 performed on the DxI 9000 Access Immunoassay Analyzer tested multiple samples in duplicate in 2 runs per day for a minimum of 20 days.

Routine Mode:

Concentration (pg/mL)			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	86	7.8	0.19	2.4	0.10	1.2	0.41	5.2	0.46	5.9
Sample 2	86	12	0.48	3.9	0.40	3.3	0.48	4.0	0.79	6.5
Sample 3	86	89	2.1	2.3	2.1	2.3	2.4	2.7	3.8	4.3
Sample 4	86	1369	44.2	3.2	15.4	1.1	18.3	1.3	50.3	3.7
Sample 5	84	2449	48.9	2.0	14.2	0.6	40.8	1.7	65.2	2.7

Concentration (pmol/L)			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	86	0.83	0.02	2.4	0.01	1.2	0.04	5.2	0.05	5.9
Sample 2	86	1.3	0.05	3.9	0.04	3.3	0.05	4.0	0.08	6.5
Sample 3	86	9.4	0.22	2.3	0.22	2.3	0.25	2.7	0.40	4.3
Sample 4	86	145	4.7	3.2	1.6	1.1	1.9	1.3	5.3	3.7
Sample 5	84	260	5.2	2.0	1.5	0.6	4.3	1.7	6.9	2.7

IntraOperative Mode:

Concentration (pg/mL)			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	88	1.7	0.15	8.6	0.13	7.3	0.12	6.9	0.23	13.2
Sample 2	88	6.6	0.27	4.1	0.03	0.4	0.19	2.9	0.33	5.0
Sample 3	88	14	0.6	4.0	0.0	0.0	0.4	2.7	0.7	4.8
Sample 4	88	34	1.3	4.0	0.0	0.0	0.5	1.4	1.4	4.2
Sample 5	88	169	5.5	3.3	3.1	1.8	2.4	1.4	6.8	4.0
Sample 6	88	1014	41.7	4.1	0.0	0.0	13.1	1.3	43.8	4.3
Sample 7	88	2542	72.3	2.8	41.7	1.6	0.0	0.0	83.5	3.3

Concentration (pmol/L)			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	88	0.18	0.02	8.6	0.01	7.3	0.01	6.9	0.02	13.2
Sample 2	88	0.70	0.03	4.1	0.003	0.4	0.02	2.9	0.03	5.0
Sample 3	88	1.5	0.06	4.0	0.0	0.0	0.04	2.7	0.07	4.8
Sample 4	88	3.6	0.14	4.0	0.0	0.0	0.05	1.4	0.15	4.2
Sample 5	88	18	0.6	3.3	0.3	1.8	0.3	1.4	0.7	4.0
Sample 6	88	107	4.4	4.1	0.0	0.0	1.4	1.3	4.6	4.3
Sample 7	88	269	7.7	2.8	4.4	1.6	0.0	0.0	8.9	3.3

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), Limit of Detection (LoD) and Limit of Quantitation (LoQ):
Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) studies were conducted on the DxI 9000 Access Immunoassay Analyzer following CLSI guideline EP17-A2. The LoB study included multiple reagent lots and 3 instruments over a minimum of 3 days. The LoD and LoQ studies included multiple reagent lots and 3 instruments over a minimum of 5 days.

ROUTINE MODE	Maximum Observed Result		Design Criteria	
	pg/mL	pmol/L	pg/mL	pmol/L
Limit of Blank (LoB)	0.5	0.05	≤ 1.0	≤ 0.11
Limit of Detection (LoD)	0.7	0.08	≤ 1.0	≤ 0.11
Limit of Quantitation (LoQ) ≤ 20% within-lab CV	0.7	0.08	≤ 1.7	≤ 0.18

INTRAOPERATIVE MODE	Maximum Observed Result		Design Criteria	
	pg/mL	pmol/L	pg/mL	pmol/L
Limit of Blank (LoB)	0.5	0.05	≤ 1.0	≤ 0.11
Limit of Detection (LoD)	0.8	0.08	≤ 1.0	≤ 0.11

INTRAOPERATIVE MODE	Maximum Observed Result		Design Criteria	
	pg/mL	pmol/L	pg/mL	pmol/L
Limit of Quantitation (LoQ) ≤ 20% within-lab CV	0.8	0.08	≤ 1.7	≤ 0.18

Method Comparison:
A study based on CLSI EP09c, 3rd Edition using Weighted Deming regression and Pearson's correlation compared the Access 2 Immunoassay System and the DxI 9000 Access Immunoassay Analyzer.

ROUTINE MODE:

N	Concentration Range* (pg/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
144	2.2 - 3278	0.97	0.96 - 0.98	-0.23	-0.33 – (-0.12)	1.00

N	Concentration Range* (pmol/L)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
144	0.23 - 347	0.97	0.96 - 0.98	-0.024	-0.035 - (-0.013)	1.00

INTRAOPERATIVE MODE:

N	Concentration Range* (pg/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
116	2.3 - 3677	1.02	1.00 - 1.04	-0.081	-0.36 - 0.20	0.99

N	Concentration Range* (pmol/L)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
116	0.24 - 390	1.02	1.00 - 1.04	-0.0086	-0.038 - 0.021	0.99

*Range is Access 2 values

Substantial Equivalence Comparison Conclusion

Beckman Coulter's Access Intact PTH assay on the DxI 9000 Access Immunoassay Analyzer (K232791) is substantially equivalent to Intact PTH assay on the Access Immunoassay System (K061190) 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.