September 5, 2023

Ortho-Clinical Diagnostics
Declan Hynes
Senior Regulatory Affairs Manager
Felindre Meadows
Pencoed
Bridgend, CF35 5PZ
United Kingdom

Re: K221197
Trade/Device Name: VITROS Immunodiagnostic Products Intact PTH II Reagent Pack
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid Hormone Test System
Regulatory Class: Class II
Product Code: CEW
Dated: January 17, 2023
Received: January 17, 2023

Dear Declan Hynes:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221197

Device Name
VITROS Immunodiagnostic Products Intact PTH II Reagent Pack

Indications for Use *(Describe)*
VITROS Immunodiagnostic Products Intact PTH II Reagent Pack quantitatively measures intact parathyroid hormone (iPTH) in human serum and plasma (K2-EDTA, lithium heparin or sodium heparin) using the automated VITROS 3600 Immunodiagnostic System.
Intact PTH is indicated to aid in the diagnosis of hyperparathyroidism, hypoparathyroidism, differential diagnosis of hypocalcemia or hypercalcemia and for intraoperative measurement of iPTH levels.

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.

The assigned 510(k) number is: K221197

1. Submitter name, address, contact

Ortho-Clinical Diagnostics,
Felindre Meadows, Pencoed, Bridgend,
United Kingdom CF35 5PZ
P: (+44) 01656 778032; F: (585) 453-3113
Contact Person: Declan Hynes

2. Preparation Date August 14th, 2023

3. Device Name: VITROS Immunodiagnostic Products Intact PTH II Reagent Pack

Product Code: CEW

Regulation: 21 CFR 862.1545 Parathyroid hormone test system.

4. Predicate Device The VITROS Immunodiagnostic Products Intact PTH II Reagent Pack is substantially equivalent to the Roche Elecsys PTH assay, K070709

5. Device Description:

The VITROS Immunodiagnostic Products Intact PTH II assay is performed using the VITROS Intact PTH II Reagent Pack and the VITROS Intact PTH II Calibrators on the VITROS 3600 Immunodiagnostic System.

VITROS Intact PTH II Reagent Pack contains:

1 reagent pack containing:

- 100 coated wells (biotinylated anti-PTH antibody, 2ug/ml).
- 7.4 mL assay reagent as buffer with bovine gamma globulin, bovine serum albumin, and antimicrobial agent.
- 7.4 mL conjugate reagent (HRP-mouse monoclonal anti-PTH, 6 ug/mL) in buffer with bovine serum albumin and antimicrobial agent).

6. Intended use: Rx ONLY

For *in vitro* diagnostic use only.

VITROS Immunodiagnostic Products Intact PTH II Reagent Pack quantitatively measures intact parathyroid hormone (iPTH) in human serum and plasma (K2-EDTA, lithium heparin or sodium heparin) using the automated VITROS 3600 Immunodiagnostic System.
Indications for use:
Intact PTH is indicated to aid in the diagnosis of hyperparathyroidism, hypoparathyroidism, differential diagnosis of hypocalcemia or hypercalcemia and for intraoperative measurement of iPTH levels.

7. Comparison with predicate:

Device Characteristic	Predicate Device Roche Elecsys PTH Assay, K070709, cleared 13 July 2007	New Device VITROS Immunodiagnostic Products Intact PTH II Reagent Pack
Intended Use	Rx ONLY For in vitro diagnostic use only. The Elecsys PTH Immunoassay is for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia. The Elecsys PTH Immunoassay can be used intraoperatively.	Same
Antibody	Mouse Monoclonal anti-PTH antibody	Same
Sample Type	Serum and Plasma	Same
Measuring Range	1.2–5000 pg/mL	6.8-5000 pg/mL
Detection Limit	Analytical Sensitivity: 1.2 pg/mL	LOB: 0.8 pg/m L LOD: 1.2 pg/mL LOQ: 1.2 pg/mL
Basic Principle	Sandwich immunoassay	Same

8. Nonclinical performance

Precision/Reproducibility:

Precision was evaluated with patient pools on the systems in the table below following the CLSI document EP05.

The data presented are a representation of test performance and are provided as a guideline.

System	Conventional & SI Units (pg/ml)					No. of Obs.	No. of Days
	Mean iPTH Conc.	Repeatability		Within Lab			
		SD	CV%	SD	CV%		
3600	16.7	0.16	0.9	0.39	2.3	80	20
	82.6	0.93	1.1	1.23	1.5	80	20
	156	1.56	1.0	2.44	1.6	80	20
	737	6.96	0.9	12.22	1.7	80	20
	2009	25.49	1.3	41.94	2.1	80	20
	4709	62.73	1.3	102.34	2.2	80	20
3600	15.9	0.14	0.9	0.39	2.4	80	20
	83.6	0.76	0.9	1.72	2.1	80	20
	154	1.27	0.8	2.25	1.5	80	20
	719	6.48	0.9	20.21	2.8	80	20
	1970	22.72	1.2	59.12	3.0	80	20
	4656	64.34	1.4	132.93	2.9	80	20

Linearity/assay measuring range:

The linearity was established in accordance with the CLSI protocol EP06.

Linearity/Measuring Range

VITROS System	Measuring (Reportable) Range
3600	6.8–5000 pg/mL (0.7–530 pmol/L)

Traceability:

Calibration of the VITROS Intact PTH II test is traceable to in-house reference calibrators, which have been value-assigned to correlate to another commercially available test.

Detection Limits:

The Limit of Blank (LoB) for the VITROS IPTH II test is 0.8 pg/mL, determined consistent with CLSI document EP17. The Limit of Detection (LoD) for the VITROS IPTH II test was determined consistent with CLSI document EP17 to be 1.2 pg/mL. The observed LoQ at 20% CV was determined to be 1.2 pg/mL, consistent with CLSI document EP17.

Analytical Specificity:

Limitations of the Procedure

Known Interferences

The VITROS Immunodiagnostic Products Intact PTH II test was screened for interfering substances at PTH concentrations of approximately 30 pg/mL (3.18 pmol/L) and 100 pg/mL (10.6 pmol/L) following CLSI EP07 [10] and EP37. [11] The substances listed in the table demonstrated observed bias of ≥10% when tested at the concentrations shown.

For substances that were tested and did not interfere, refer to "Substances that do not Interfere."

Interferent	Conventional Units		Alternate Units		% Bias
	PTH Conc. (pg/mL)	Interferent Concentration	PTH Activity (pmol/L)	Interferent Concentration	
Cefoxitin Sodium*	30	174.25 mg/dL	3.18	3877.4 µmol/L	-11.4
Rheumatoid Factor (RF)		675 IU/mL		N/A	13.5
Total protein		11.8 .g/dL		118 g/L	-14.3
Cefoxitin Sodium*	100	174.25 mg/dL	10.6	3877.4 µmol/L	-12.2
Rheumatoid Factor (RF)		900 IU/mL		N/A	6.3
Total Protein		11.9 g/dL		119 g/L	-14.0

* The level of interference for Cefoxitin Sodium is within the therapeutic range for this compound and could lead to lower reported PTH concentrations for patients on this compound.

Other Limitations

- The results from this test should be used and interpreted only in the context of the overall clinical picture.
- The VITROS Intact PTH II test will detect non-intact PTH molecules, such as the large C-terminal PTH fragment 7–84. PTH fragments, including 7–84, may cause falsely elevated PTH results in patients with abnormal renal function as these patients may have various concentrations of PTH fragments in their blood. In patients with atypical renal function, interpret the PTH result with caution, and do not make patient management decisions on the PTH result alone. [12] A study describing PTH fragmentation is provided in Lopez et al "Selected Reaction Monitoring Mass Spectrometric Immunoassay Responsive to Parathyroid Hormone and Related Variants." [13]
- Heterophile as well as human anti-animal antibodies (most common human anti-mouse antibodies or HAMA) in serum or plasma of certain individuals are known to cause interference with immunoassays [14]. The anti-animal antibodies may be present in blood samples from individuals regularly exposed to animals or who have received preparations of mouse monoclonal antibodies for diagnosis or therapy. Results inconsistent with clinical observations indicate the need for additional testing.
- Patients taking Cefoxitin Sodium could have reported PTH concentrations that are negatively biased at levels indicated in the Known Interferences section.
- Rheumatoid factor concentrations less than 450 IU/mL have demonstrated no observed interference. Rheumatoid factor at concentrations of 675 IU/mL and above have been shown to falsely elevate PTH test results.
- Total protein at concentrations less than 9.4 g/dL have demonstrated no observed interference. Total protein at concentrations of 11.8 g/dL and above have been shown to

falsely decrease PTH test results.

- The VITROS Intact PTH II test has no high dose hook effect up to a concentration of 837800 pg/mL (88807 pmol/L).

Specificity

Substances that Do Not Interfere

The substances listed in the table below were tested with the VITROS Intact PTH II test following CLSI EP07and EP37 and found not to cause bias > 10% at PTH concentrations of approximately 30 pg/mL (3.18 pmol/L) and 100 pg/mL (10.6 pmol/L) at the test concentrations shown.

Substance	Concentration	
Acetaminophen	15.6 mgdL	1033 µmol/L
Acetylcysteine	15.0 mg/dL	920 µmol/L
Albuterol (salbutamol)	0.0045 mg/dL	0.188 µmol/L
Alendronate sodium	33.21 µg/dL	N/A
Aliskiren	255 µg/dL	N/A
Alprazolam	0.0258 mg/dL	0.835 µmol/L
Amitriptyline HCl	0.0542 mg/dL	1.73 µmol/L
Amlodipine besylate	0.104 mg/dL	0.183 µmol/L
Amoxicillin	5.40 mg/dL	148 µmol/L
Ascorbic acid	5.25 mg/dL	298 µmol/L
Atorvastatin calcium trihydrate	0.162 mg/dL	1.34 µmol/L
Benazepril HCl	0.044 mg/dL	0.954 µmol/L
Bilirubin, conjugated	40.0 mg/dL	N/A
Bilirubin, unconjugated	40.0 mg/dL	N/A
Biotin	0.351 mg/dL	14.3 µmol/L
Caffeine	10.8 mg/dL	556 µmol/L
Calcitriol	0.432 µg/dL	N/A
Carbamazepine	4.5 mg/dL	190 µmol/L
Ceftriaxone disodium hemi (heptahydrate)	0.99 mg/dL	1510 µmol/L
Cephalexin sodium	13.4 mg/dL	363 µmol/L
Cholesterol	400 mg/dL	10.3 mmol/L
Cinacalcet Hydrochloride	0.0259 mg/dL	0.657 µmol/L
Ciprofloxacin	1.2 mg/dL	36.2 µmol/L
Clarithromycin	0.720 mg/dL	9.63 µmol/L
Cotinine	0.240 mg/dL	13.6 µmol/L

Substance	Concentration	
Dextran	2400 mg/dL	600 µmol/L
Dextromethorphan	0.00156 mg/dL	0.0575 µmol/L
Digoxin	0.0039 mg/dL	0.0499 µmol/L
Diphenhydramine HCl	0.0884 mg/dL	3.03 µmol/L
Dipyrone (4-methylaminoantipyrine)	3.30 mg/dL	152 µmol/L
Enalaprilat	0.0819 mg/dL	2.35 µmol/L
Epoetin alfa	20,000 mU/mL	N/A
Equilin	1.50 mg/dL	5539 µmol/L
Estrone	0.0297 µg/dL	0.0011 µmol/L
Ethylenediaminetetraacetic acid dipotassium salt (EDTA)	0.137 mg/dL	3.39 µmol/L
Ethanol	600 mg/dL	130,000 µmol/L
Fibrinogen	1000 mg/dL	29.4 µmol/L
Fluoxetine	0.142 mg/dL	4.59 µmol/L
Fosrenol (Lanthanum Carbonate)	0.300 µg/dL	N/A
Furosemide	1.59 mg/dL	48.1 µmol/L
Glyburide	0.072 mg/dL	1.46 µmol/L
Guaifenesin	0.450 mg/dL	22.7 µmol/L
Hemoglobin	1000 mg/dL	10.0 g/L
Human Anti-Mouse Antibodies (HAMA)	800 ug/L	0.005 µmol/L
Hydrochlorothiazide	0.113 mg/dL	3.79 µmol/L
Herarin (Lithium or Sodium)	330 units/dL	N/A
Ibuprofen	21.9 mg/dL	1060 µmol/L
L-dopa (Levodopa)	0.75 mg/dL	38.0 µmol/L
Levothyroxine	0.0429 mg/dL	0.552 µmol/L
Loratadine	0.0087 mg/dL	0.271 µmol/L
Naproxen sodium	39.3 mg/dL	1560 µmol/L
Nifedipine	0.0588 mg/dL	1.70 µmol/L
Omeprazole	0.84 mg/dL	24.3 µmol/L

Substance	Concentration	
Oxycodone HCl	0.0362 mg/dL	1.03 µmol/L
Paricalcitol	0.750 µg/dL	N/A
Phenytoin	6.00 mg/dL	238 µmol/L
Prednisone	0.0099 mg/dL	0.276 µmol/L
Propranolol HCl	0.115 mg/dL	3.88 µmol/L
Pseudopehedrine	0.330 mg/dL	20.0 µmol/L
Ranitidine HCl	1.17 mg/dL	33.4 µmol/L
Rifampicin (Rifampin)	4.80 mg/dL	58.3 µmol/L
Salicyclic Acid	2.86 mg/dL	207 µmol/L
Sodium Azide	100 mg/dL	15,382 µmol/L
Spironolactone	0.0555 mg/dL	1.33 µmol/L
Terazosin	0.0273 mg/dL	0.579 µmol/L
Triamterene	0.0585 mg/dL	2.31 µmol/L
Triglycerides, total	1500 mg/dL	(16.9 mmol/L)
Vancomycin hydrochloride	12.3 mg/dL	82.8 µmol/L
Warfarin sodium	8.03 mg/dL	243 µmol/L

Cross-Reactivity

The cross-reactivity of the VITROS Immunodiagnostic Products Intact PTH II test was evaluated by adding the following substances to serum samples containing no PTH.

Test Substance	Concentration	Mean Cross-reactant Sample Result		% Cross-reactivity
		pg/mL	pmol/L	
Alkaline Phosphatase	120 ng/mL	ND*	ND*	ND*
β-Cross laps	10 ng/mL	ND*	ND*	ND*
Calcitonin	100,000 pg/mL	ND*	ND*	ND*
Osteocalcin	50 ng/mL	ND*	ND*	ND*
PTH 1–34	100,000 pg/mL	ND*	ND*	ND*
PTH 39–84	100,000 pg/mL	ND*	ND*	ND*
PTH 7–84	1000 pg/mL	613.2	65.0	61.3

*Not Detectable (ND). Concentration was below the measuring interval of the test, 6.8–5000 pg/mL (0.7–530 pmol/L).

The cross-reactivity of the VITROS Immunodiagnostic Products Intact PTH II test was evaluated by adding the following substances to serum samples containing PTH at a concentration of approximately 30 pg/mL (3.18 pmol/L).

Test Substance	Concentration	Mean Control Sample Result		Mean Cross-reactant Sample Result		% Cross-reactivity
		pg/mL	pmol/L	pg/mL	pmol/L	
Alkaline Phosphatase	120 ng/mL	26.3	2.8	26.3	2.8	0.0
β-Cross laps	10 ng/mL	26.3	2.8	26.6	2.8	0.0
Calcitonin	100,000 pg/mL	26.3	2.8	26.5	2.8	0.0
Osteocalcin	50 ng/mL	26.3	2.8	26.1	2.8	0.0
PTH 1–34	100,000 pg/mL	26.3	2.8	21.4	2.3	0.0
PTH 39–84	100,000 pg/mL	26.3	2.8	16.5	1.8	0.0
PTH 7–84	1000 pg/mL	27.7	2.7	778.8	75.1	75.1

Assay cut-off:
Not applicable.

Comparison studies:

Method comparison with predicate device:
Accuracy was evaluated consistent with CLSI document EP09. The table shows the results of a method comparison study using patient (serum) samples analyzed on the VITROS iPTH II assay compared with those analyzed on a commercially available PTH assay.

Regression Results – VITROS Intact PTH II on the VITROS 3600 Immunodiagnostic System versus a Commercially available PTH assay

System	n	Slope	Correlation Coefficient	Conventional and SI Units (pg/mL)		Alternate Units (pmol/L)	
				Range of Sample Conc	Intercept	Range of Sample Conc	Intercept
VITROS 3600 vs. Comparative Method	206	1.01	0.991	7.7–4384	0.3	0.8–464.7	0.0

Matrix comparison:

The results met the acceptance criteria for the comparison between serum and plasma (serum, K2-EDTA, Li-Hep, and Na-Hep) specimens spanning the expected measuring interval. The serum and plasma specimen matrices tested were determined to be equivalent. Based on the analysis, serum and plasma (K2-EDTA, Li-Hep, and Na-Hep) are suitable specimen matrices for use with the VITROS Intact PTH II assay.

Passing and Bablok Regression	Li-Hep Plasma	Na Hep Plasma	EDTA Plasma
Slope	1.011	1.009	0.988
Corr. Coef r	0.996	0.994	0.973
N	84	84	84

Specimens Recommended

Serum, Plasma K2-EDTA, Li-Heparin, and Na-Heparin

Specimens Not Recommended

Do not use turbid specimens. Turbidity in specimens may affect test results.

Do not use hemolysed samples as hemolysis may affect test results.

Clinical studies:

a. Clinical Sensitivity:
Not applicable.
b. Clinical Specificity:
Not applicable.
c. Other clinical supportive data:

A clinical study was performed to confirm the effectiveness of the VITROS Intact PTH II assay for Intra-operative (IO) use. Sets of specimens from 32 subjects that qualified for the primary endpoints (described below), that met the inclusion criteria, and which were not excluded based on exclusion criteria, were analyzed using the VITROS Intact PTH II assay on the VITROS 3600 Immunodiagnostic system.

The following Inclusion/Exclusion criteria were used:

Inclusion Criteria

- Men and women >21 years of age.
- Undergoing first parathyroidectomy procedure with intra-operative parathyroid (PTH) testing.
- Able to provide a minimum of 5ml of blood per collection timepoint, with a maximum of 10 mL blood per collection timepoint.

Exclusion Criteria

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- Known HIV infection.
- Individuals who are unable to provide informed consent.
- Individuals unable to provide a minimum sample volume of 5ml of whole blood per timepoint.

Specimens underwent testing in single replicates on both the VITROS Intact PTH II assay and the comparator (hospital's) assay.

For this clinical study, the following criterion was utilized to determine 'success'.

Success Criterion: A successful surgery is defined to be a 50% or greater drop in PTH level from the greater of the pre-incision or pre-excision baseline values to the post-excision test result after the last parathyroid gland excision.

The analyses were based on agreement between the VITROS Intact PTH II assay (investigational device) and the assays used by participating surgeons/sites (comparator devices cleared by the FDA for use intra-operatively), utilizing the same criteria of a successful surgery for each. Concordance between the hospital's assay and the VITROS Intact PTH II assay is presented in the table below.

		PTH Assay Used During Surgery	
		Successful	Unsuccessful
VITROS Intact PTH II	Successful	29	0
	Unsuccessful	0	3

Primary Endpoint Positive Agreement = 29/29 = 100%
Primary Endpoint Negative Agreement = 3/3 = 100%
Primary Endpoint Overall Agreement = 32/32 = 100%

Clinical cut-off:

Not applicable.

Expected values/Reference range:

It is recommended that each laboratory establish its own reference interval for the population it serves. The VITROS Immunodiagnostic Products Intact PTH II test 95% Reference Interval was established, based on 134 self-reported healthy donors.

Subjects were excluded if they met any of the following exclusion criteria:

- Family history of parathyroid or calcium regulatory disease.
- Personal history of kidney disease, GI disease, liver disease, endocrine disease, parathyroid disease, seizures, osteoporosis or bone disease.
- Use of drugs that affect calcium, phosphorus, vitamin D/bone metabolism or vitamin D absorption or the use of drugs that have been reported to interfere with PTH tests.
- Additional testing conducted to exclude subjects based on following criteria:
    - Calcium: 8.4 – 10.2 mg/dL
    - Magnesium: 1.6 – 2.3 mg/dL
    - Alkaline phosphatase: 38 – 126 U/L
    - Phosphate: 2.5 – 4.5 mg/dL
    - TSH: 0.465 – 4.68 mIU/L

Reference Interval

It is recommended that each laboratory establish its own reference interval for the population it serves.

The VITROS Intact PTH II test 95% Reference Interval was established, based on 134 self-reported healthy donors.

The lower and upper reference limits are shown in the table below.

VITROS Intact PTH II test 95% Reference Interval

N	Conventional Units (pg/mL)	Alternate Units (pmol/L)
134	14.5-79.4	1.5 - 8.4

This reference interval is the central 95% of results of a study of 134 patients with normal calcium, magnesium, alkaline phosphatase, phosphate and TSH values.

8. Proposed Labeling: The labeling is sufficient, and it satisfies the requirements of 21 CFR Part 809.10.

9. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.