510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
k051141

B. Purpose for Submission:
New Device

C. Measurand:
Whole Parathyroid Hormone (PTH)

D. Type of Test:
Immunochemiluminometric assay (ICMA)

E. Applicant:
Scantibodies Laboratory, Inc.

F. Proprietary and Established Names:
Whole PTH (1-84) Specific Immunochemiluminometric Assay

G. Regulatory Information:

1. Regulation section:
   21 CFR §862.1545, Radioimmunoassay Parathyroid Hormone

2. Classification:
   Class II

3. Product code:
   CEW

4. Panel:
   75 (Chemistry)

H. Intended Use:

1. Intended use(s):
   See Indications for Use below.
2. Indication(s) for use:
   The Scantibodies Laboratory, Inc. Whole Parathyroid Hormone (PTH) test system is a device intended to measure parathyroid hormone in plasma. PTH measurements are used in the differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) and hypocalcemia (abnormally low levels of calcium in the blood) resulting from disorders of calcium metabolism.

3. Special conditions for use statement(s):
   This kit has been designed for the quantitative determination of human whole parathyroid hormone (PTH) without cross-reaction to PTH (7-84) fragments in plasma samples.

4. Special instrument requirements:
   Microplate luminometer equipped with dual injectors capable of delivering 100µl each.

I. Device Description:

The Scantibodies Whole PTH Kit includes the following: PTH Standards (7 vials), PTH Controls (2 vials), PTH Antibody Coated Plate (1) 12 strips, Whole PTH Tracer ICMA (1 vial), Wash Concentrate (1 bottle), Trigger 1 (1 bottle), Trigger 2 (1 bottle).

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Scantibodies Laboratory, Inc. Whole PTH (1-84) Specific Immunoradiometric (IRMA) Assay.

2. Predicate 510(k) number(s):
   k001411

3. Comparison with predicate:

   Comparison table for new device compared to the predicate device

Comparison of device to predicate		
Item	**New Device Whole PTH (ICMA) k051141**	**Predicate Device Whole PTH (IRMA) k001411**
Intended Use	Assay used to detect human parathyroid hormone in human blood sample without cross reaction to PTH (7-84) fragment	Assay used to detect human parathyroid hormone in human blood sample without cross reaction to PTH (7-84) fragment
Specimen	EDTA – Plasma	EDTA – Plasma
Assay Format	ICMA	IRMA
Result Read Time	2 – 2.5 hours	18 – 24 hours
Analytical Sensitivity	˜ 1.2 pg/mL	˜ 1.0 pg/mL
Normal Range	5 – 33 pg/mL	5 – 39 pg/mL
Solid Phase	Antibody Coated Plates – luminol – Ab conjugate	Antibody Coated Beads

K. Standard/Guidance Document Referenced (if applicable):

NCCLS Guideline EP6-A.
NCCLS Guideline (C28-A)

L. Test Principle:

The Scantibodies Whole PTH Kit is an immunochemiluminometric assay (ICMA) utilizing polyclonal PTH antibodies directed against N-terminal PTH and C-terminal PTH. The anti-PTH N-terminal region specific antibody is labeled with luminol. The antibody directed against C-terminal PTH (39-84 fragment) is bound to the wells of the micro titer plate. Whole PTH (CAP) in patient samples is bound both to the wells and to the luminol-PTH antibody. After incubation, free and bound luminol-antibody fractions are separated by discarding the supernatant. Wash steps reduce non-specific binding (NSB). The concentration of Whole PTH (CAP) is directly proportional to the photons emitted from the wells upon addition of triggering regents. The concentration of PTH in unknown patient samples and controls is determined by interpolation using a calibration curve.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The inter-assay precision was evaluated by performing 20 separate whole PTH (CAP) assays on three samples in duplicate over a two week period. The inter-assay precision is presented in the table below.

Precision (inter-assay)			
Sample	Mean Value (pg/mL)	SD (pg/mL)	%CV
1	58.0	5.12	8.83
2	192.6	13.86	7.07
3	496.1	37.45	7.55

The intra-assay precision was also evaluated by performing 20 replicates in the Whole PTH (CAP) assays on three samples. The intra-assay precision is presented in the table below.

Precision (intra-assay)				
Kit Batch	Sample	Mean Value (pg/mL)	SD (pg/mL)	% CV
1	1	50.70	3.62	7.1
	2	188.81	7.26	3.9
	3	469.31	38.23	8.2
2	1	42.30	2.19	5.2
	2	157.91	7.87	5.0
	3	476.00	36.62	7.7
3	1	59.18	2.81	4.7
	2	181.87	7.00	3.9
	3	420.76	13.84	3.3

b. Linearity/assay reportable range:

The high dose hook response of the Scantibodies Laboratory, Inc. Whole PTH (1-84) Specific ICMA Diagnostic Kit was determined as 20,000 pg/mL of Whole PTH (CAP). Samples greater than the highest standard (approximately 2300 pg/mL) and up to 20,000 pg/mL Whole PTH (CAP) will produce RLU values greater than that of the highest standard.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The traceability of controls and standards is not available through NIST or WHO for PTH, the sponsor indicated that they rely on the "primary standards" prepared during validation which are traceable to the predicate device. Values are assigned by testing new lots a minimum of 5 times using multiple analysts over multiple days. The average values obtained when tested against lyophilized "primary standards" were used for the value assignment of the standards.

New lots of controls were value assigned by assaying the controls a minimum of 5 times using multiple analysts over multiple days. A value of +/- 20% of the average of the data obtained was calculated and applied to both control I (low control) and control II (high control).

The Scantibodies PTH Calibrators were prepared analytically on a mass basis from purified synthetic Whole PTH (1-84). These standards are further evaluated against lyophilized "primary standards" which are stored at -70° C to maintain potency.

d. Detection limit:

The detection limit of the assay is defined as the lowest measurable value distinguishable from calibrator A. This sensitivity was determined by assaying calibrator A 20 times in the same assay. The analytical sensitivity was 0.54

pg/mL. The minimum detectable concentration was approximately 1.2 pg/mL at 2 standard deviations above the first PTH calibrator.

e. Analytical specificity:
The Scantibodies Whole PTH (CAP) assay did not show cross-reaction to PTH (7-84) fragment when the synthetic PTH (7-84) peptide was serially diluted with standard A matrix and assayed.

PTH (7-84) Conc. Sample (pg/mL)	Measured PTH Conc. (pg/mL)
2500	Undetected
5000	Undetected
10000	Undetected
20000	Undetected

Interferences:
The sponsor indicated that specimens containing up to 250 mg/dL triglyceride, 15 mg/dL hemoglobin and 30 mg/dL bilirubin did not exhibit any significant effect on the assay. However it is strongly recommended that grossly hemolyzed or lipemic samples should not be used in this assay.

f. Assay cut-off:
Not Applicable for this type of device.

2. Comparison studies:
   a. Method comparison with predicate device:

   The comparison study was conducted by preparing 3 different lots of whole PTH ICMA Kits which included multiple lots of components to introduce adequate variations in manufacturing. Samples of EDTA plasma were drawn from 120 normal donors and 120 dialysis donors with elevated levels of PTH.

   All samples were tested on both the Whole PTH ICMA Kit and the predicate Whole PTH IRMA Kit with no data exclusions.

   Data was compiled into 3 categories: Normal, Patient, All Samples (all samples represent a compilation of the Normal and Patient samples). Correlation data was evaluated from the 3 categories. For Normal samples a total of 62% of the samples were from male donors. The linear correlation with the predicate device is $y = 1.03x + 1.45$ with $R = 0.948$. For donors on dialysis 54.2% of the samples were from male donors. The linear correlation with the predicate device is $y = 0.96x + 2.63$ with $R = 0.974$. The overall correlation with the predicate is $y = 0.96 + 2.64$ with $R = 0.966$.

   b. Matrix comparison:
   Not applicable - this device is intended for use with plasma samples only

3. Clinical studies:
   a. Clinical Sensitivity:
   Not applicable

   b. Clinical specificity:
   Not applicable

   c. *Other clinical supportive data (when a. and b. are not applicable):*

4. Clinical cut-off:
   Not applicable for this type of device

5. Expected values/Reference range:
   The normal value range was determined following the NCCLS guidelines (C28-A) using 120 samples from apparently healthy individuals. It is recommended that each laboratory establish its own range of normal values. The values given are only indicative and may vary from other published data.

Patient Classification	Whole PTH Range (pg/mL)
Normal	5-33
Hyperparathyroidism	>33

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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