510(k) Summary

LIAISON® N-TACT® PTH Gen II
LIAISON® N-TACT® PTH Gen II Control Set
LIAISON® N-TACT® PTH Gen II Calibration Verifiers

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

1. 510(k) Number: k132515

2. Applicant: Carol A. DePouw
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3. Date: September 4, 2013

4. Proprietary and Established Names:

LIAISON® N-TACT® PTH Gen II
LIAISON® N-TACT® PTH Gen II Control Set
LIAISON® N-TACT® PTH Gen II Calibration Verifiers

NOV 0 8 2013

5. Regulatory Information:

LIAISON® N-TACT® PTH Gen II

Regulation Section: 21 CFR 862.1545
Classification: Class II
Product Code: CEW
Panel: Clinical Chemistry (75)

LIAISON® N-TACT® PTH Gen II Control Set
LIAISON® N-TACT® PTH Gen II Calibration Verifiers

Regulation Section: 21 CFR 862.1660
Classification: Class I, reserved
Product Code: JJX
Panel: Clinical Chemistry (75)

6. Predicate Devices:

The predicate device used to demonstrate substantial equivalence to the LIAISON® N-TACT® PTH Gen II is the Siemens ADVIA® CENTAUR INTACT Parathyroid Hormone (iPTH) Assay previously cleared under k020217.

The predicate device used to demonstrate substantial equivalence to the LIAISON® N-TACT® PTH Gen II Control Set is the LIAISON® N-TACT® PTH Control Set previously cleared under k033426.

The predicate device used to demonstrate substantial equivalence to the LIAISON® N-TACT® PTH Gen II Calibration Verifiers is the LIAISON® N-TACT® PTH Calibration Verifiers previously cleared under k093498.

7. Device Description:

The LIAISON® N-TACT® PTH Gen II assay is a modified two-step, two-site sandwich assay that uses two goat polyclonal antibodies for capture and detection of intact PTH. Results are determined by a 2 point calibration conversion of the master curve to a working curve. The light signal is measured by a photomultiplier as relative light units (RLU) and is proportional to the concentration of intact PTH present in the calibrators, controls or samples.

LIAISON® N-TACT® PTH Gen II Control set contains;

- 2 levels controls containing 80% human plasma spiked with 1-84 PTH, and preservatives; 4 vials each level; lyophilized

The target concentration for control level 1 is 20 pg/mL.
The target concentration for control Level 2 is 300 pg/mL.

The range of concentrations of each control is reported on the certificate of analysis provided with each LIAISON® N-TACT® PTH Gen II Control set.

LIAISON® N-TACT® PTH Gen II Calibration Verifier set contains:

- 4 levels containing 80% human plasma spiked with 1-84 PTH, with preservative, 1 vial each level, lyophilized

The target concentration for cal verifier A is 10 pg/mL.
The target concentration for cal verifier B is 150 pg/mL.
The target concentration for cal verifier C is 650 pg/mL.
The target concentration for cal verifier D is 1600 pg/mL.

The range of concentrations of each calibration verifier is reported on the certificate of analysis provided with each LIAISON® N-TACT® PTH Gen II Calibration Verifier set.

8. Intended Use:

The LIAISON® N-TACT® PTH Gen II is an *in vitro* chemiluminescent immunoassay (CLIA) intended for the quantitative determination of intact human parathyroid hormone in serum, EDTA and Lithium Heparin plasma samples. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia and hypocalcemia resulting from disorders of calcium metabolism.
The test is to be performed on the LIAISON® XL Analyzer.

The LIAISON® N-TACT® PTH Gen II Control Set is intended for use as assayed quality control samples to monitor the accuracy and precision of the DiaSorin LIAISON® N-TACT® PTH Gen II assay.

The LIAISON® N-TACT® PTH Gen II Calibration Verifiers are assayed quality control materials intended for the quantitative verification of calibration and reportable range of the LIAISON® N-TACT® PTH Gen II assay.

9. Indication(s) for Use:

Same as Intended Use

10. Substantial Equivalence Information:

Both the LIAISON® N-TACT® PTH Gen II and the predicate Siemens ADVIA CENTAUR® INTACT Parathyroid Hormone (iPTH) Assay are prepackaged reagents for use on automated clinical chemistry analyzers. A comparison of the similarities and differences between the devices are provided in the following table:

Assay Similarities and Differences		
Characteristic	Candidate Device LIAISON® N-TACT® PTH Gen II	Predicate Device ADVIA Centaur iPTH (K020217)
Intended Use	For in vitro quantitative determination of intact human parathyroid hormone	For in vitro quantitative determination of intact parathyroid hormone
Measured Analyte	Intact Parathyroid Hormone	Intact Parathyroid Hormone
Calibration	Two-point calibration	Two-point calibration
Antibody	Goat polyclonal	Goat polyclonal
Reagent Storage	On-board or in refrigerator @ 2-8°C	On-board or in refrigerator @ 2-8°C
Measuring range	3 – 1900 pg/mL	2.5 – 1900 pg/mL
Sample Matrix	EDTA Plasma, Serum, SST serum and Lithium Heparin plasma	EDTA Plasma and Serum
Sample size	150 µL	200 µL
Open storage on analyzer	56 days	28 days
Calibration interval	28 days	14 days
Calibrators	2 levels – Included with kit	2 Levels – Not included with kit
Manufacturers Controls	2 levels	3 levels
Reference range	14.5 – 87.1 pg/mL	11.1 – 79.5 pg/mL

Control Similarities and Differences		
Characteristic	Candidate Device LIAISON® N-TACT® PTH Gen II Control Set	Predicate Device LIAISON® N-TACT® PTH Control Set (k033426)
Intended Use	intended for use as assayed quality control samples to monitor the accuracy and precision of the LIAISON® N-TACT® PTH Gen II	intended for use as assayed quality control samples to monitor the accuracy and precision of the LIAISON® N-TACT® PTH
Storage	Store at 2-8°C until ready to use	Same
Levels	2 levels: lyophilized Level 1 (approx 20 pg/mL) Level 2 (approx 300 pg/mL)	2 levels: lyophilized Level 1 (approx 60 pg/mL) Level 2 (approx 560 pg/mL

Calibration Verifiers Similarities and Differences		
Characteristic	Candidate Device LIAISON® N-TACT® PTH Gen II Calibration Verifiers	Predicate Device LIAISON® N-TACT® PTH Calibration Verifiers (k093498)
Intended Use	assayed quality control materials intended for the quantitative verification of calibration and reportable range of the LIAISON® N-TACT® PTH Gen II	assayed quality control materials intended for the quantitative verification of calibration and reportable range of the LIAISON® N-TACT® PTH
Storage	2 to 8°C	Same
Levels	4 levels; lyophilized Cal Ver A (approx 10 pg/mL) Cal Ver B (approx 150 pg/mL) Cal Ver C (approx 650 pg/mL) Cal Ver D (approx 1600 pg/mL)	4 levels; lyophilized Cal Ver A (approx 20 pg/mL) Cal Ver B (approx 150 pg/mL) Cal Ver C (approx 350 pg/mL) Cal Ver D (approx 1500 pg/mL)
Volume	2.0 mLs	Same

11. Standard/guidance Document Reference:

- CLSI Guideline EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods;
- CLSI Guideline EP6-A, Evaluation of Linearity of Quantitative Analytical Methods;
- CLSI Guideline EP7-A2, Interference Testing in Clinical Chemistry;
- CLSI Guideline EP9-A2-IR, Method Comparison and Bias Estimation Using Patient Samples;
- CLSI Guideline EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures;
- CLSI Guideline C28-A3, Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory.

12. Performance Characters:

Method Comparison

A method comparison study was performed following CLSI EP9-A2, individual results for the Siemens ADVIA Centaur® Intact PTH (iPTH) and the LIAISON® N-TACT® PTH

Gen II were plotted. Passing & Bablok linear regression analyses were performed and gave the following results:

Passing & Bablok Fit					
n	Slope	95% CI	Intercept pg/mL	95% CI	Correlation coefficient (r)
198	1.010	0.99 to 1.03	-1.5851	-3.11 to -0.44	0.9953

Sample Matrix Comparison

Sixty-five (65) matched patient sets of EDTA plasma, serum, SST serum, and Lithium Heparin plasma samples were tested to determine if these sample types provide equivalent results on the LIAISON® N-TACT® PTH Gen II assay. The following Passing & Bablok linear regression results were obtained:

EDTA plasma vs.	**Slope**	**95% CI**	**Intercept pg/mL**	**95% CI**	**R^2**
Serum	0.97	0.94 to 1.0	-2.45	-4.05 to -1.51	0.9986
SST Serum	1.01	0.99 to 1.03	-2.25	-3.10 to -1.44	0.9996
Lithium Heparin	0.98	0.97 to 1.01	-0.01	-1.05 to 0.74	0.9991

Reference Range

EDTA plasma samples from125 apparently healthy adults aged 21 - 70 years of age from mixed ethnic backgrounds (32.5% dark -skinned, 66.7% light-skinned and 0.8% unknown) with normal Total Calcium, TSH, Phosphorus, Magnesium, Creatinine, Alkaline Phosphatase and 25 OH Vitamin D values from the northern and southern regions of the U.S.

LIAISON® N-TACT® PTH Gen II Reference Range

Population(n =125)	Median PTH (pg/mL)	Observed Range 2.5^{th} to 97.5^{th} Percentile
United States	34.00	14.5 – 87.1 pg/mL

Precision

Precision testing was performed following CLSI Guideline EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition. A coded panel comprised of 7 frozen EDTA plasma samples spanning the assay range and 2 lots of LIAISON® N-TACT® PTH Gen II controls (2 levels) were tested in the study. The precision panel samples and kit controls were tested on two lots of LIAISON® N-TACT® PTH Gen II in two replicates per run, 2 runs per day for 20 operating days for a total of 160 replicate results per sample. The 20 day results are summarized for the combined reagent lot numbers as sample mean PTH concentration in pg/mL, standard deviations and coefficient of variation (%CV) for between lot and Total across lots.

Sample ID	n	Mean PTH (pg/mL)	Between-Lot		Total (Across Lots)	
			SD	%CV	SD	%CV
Lot 1 Kit Control Level 1	160	19.3	0.26	1.3%	0.65	3.3%
Lot 1 Kit Control Level 2	160	250	9.27	3.7%	8.84	3.5%
Lot 2 Kit Control Level 1	160	18.5	0.28	1.5%	0.57	3.1%
Lot 2 Kit Control Level 2	160	252	10.59	4.2%	9.05	3.6%
EDTA Plasma 1	160	12.6	0.23	1.8%	0.53	4.2%
EDTA Plasma 2	160	34.5	0.70	2.0%	1.38	4.0%
EDTA Plasma 3	160	86.2	1.68	1.9%	3.07	3.6%
EDTA Plasma 4	160	156.1	5.25	3.4%	5.54	3.5%
EDTA Plasma 5	160	605	24.62	4.1%	19.37	3.2%
EDTA Plasma 6	160	1348	46.58	3.5%	44.06	3.3%
EDTA Plasma 7	160	1477	84.06	5.7%	40.62	2.8%

Linearity

One sample pool of each type; serum, SST serum, EDTA plasma and Lithium Heparin plasma were diluted and analyzed by the LIAISON® N-TACT® PTH Gen II assay following CLSI EP6-A. The results were analyzed by a weighed Deming regression of Observed PTH Concentration versus Expected PTH Concentration.

The resulting equations for each sample types are:
Serum: Observed PTH = 0.9767x - 3.624; R^2 = 0.9982
SST Serum: Observed PTH = 0.9742x + 3.856; R^2 = 0.9987
EDTA plasma: Observed PTH = 1.012x – 4.127; R^2 = 0.9983
Lithium Heparin plasma: Observed PTH = 0.9461x + 3.696; R^2 = 0.9992

High Dose Hook Effect

Testing was conducted to determine if the LIAISON® N-TACT® PTH Gen II assay is susceptible to artificially low results in the presence of very high levels of PTH (Hook Effect). A zero sample was spiked with enough 1-84 PTH to equal concentrations above the assay measuring range of 1900 pg/mL.

No hook effect was observed up to 1,000,000 pg/mL of PTH.

Recovery Study

Five (5) high concentration EDTA plasma samples and 5 low concentration samples EDTA plasma samples were analyzed neat on the LIAISON® N-TACT® PTH Gen II assay. Recovery samples were then prepared by mixing defined ratios of the high and low samples and tested in replicates of 5. The observed values were compared to the expected values to determine the % recovery.

	Defined	Expected	Observed	% Recovery
High Sample 1 (HS1)	999			
2 HS1 : 1 LS1		695	674	97%
1 HS1 : 1 LS1		539	523	97%
1 HS1 : 2 LS1		383	358	93%
Low Sample 1 (LS1)	79.8			
High Sample 2 (HS2)	1416			
2 HS2 : 1 LS2		1003	992	99%
1 HS2 : 1 LS2		790	794	100%
1 HS2 : 2 LS2		577	590	102%
Low Sample 2 (LS2)	164			
High Sample 3 (HS3)	696			
2 HS3 : 1 LS3		479	495	103%
1 HS3 : 1 LS3		367	369	101%
1 HS3 : 2 LS3		255	237	93%
Low Sample 3 (LS3)	37.7			
High Sample 4 (HS4)	1630			
2 HS4 : 1 LS4		1174	1118	95%
1 HS4 : 1 LS4		939	906	96%
1 HS4 : 2 LS4		704	668	95%
Low Sample 4 (LS4)	248			
High Sample 5 (HS5)	46.4			
2 HS5 : 1 LS5		32.6	30.3	93%
1 HS5 : 1 LS5		25.5	23.8	93%
1 HS5 : 2 LS5		18.4	18.4	100%
Low Sample 5 (LS5)	4.7			
		Mean Recovery		97%

Analytical Specificity

Cross-Reactivity Studies

CLSI Guideline EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline; Second Edition.

Controlled studies of potentially cross-reacting substances were performed on the LIAISON® N-TACT® PTH Gen II assay at the concentrations listed below.

Cross-Reactant	Spiked Concentration	% Cross Reactivity
PTH (7 – 84)	1200 pg/mL	53%
PTH (1 – 34)	200,000 pg/mL	< 0.01%
PTH (39 - 68)	200,000 pg/mL	< 0.01%
PTH (44 – 68)	200,000 pg/mL	< 0.01%
PTH (39 – 84)	200,000 pg/mL	< 0.01%
PTH (53 – 84)	200,000 pg/mL	< 0.01%
Calcitonin	200,000 pg/mL	< 0.01%
C-Telopeptide (β crosslaps)	200,000 pg/mL	< 0.01%
Osteocalcin	200,000 pg/mL	< 0.01%

Interference Studies

Controlled studies of potentially interfering endogenous substances performed in EDTA plasma at two PTH levels (70 and 150 pg/mL) showed no interference in the

LIAISON® N-TACT® PTH Gen II at the highest concentration for each substance listed below.

Drug/Substance	Concentration at which no significant interference (≥ ±10%) was observed
Hemoglobin	500 mg/dL
Bilirubin (conjugated)	40 mg/dL
Bilirubin (unconjugated)	20 mg/dL
Triglycerides	3,000 mg/dL
Cholesterol	500 mg/dL
Albumin	12 g/dL
Rheumatoid Factor	2760 ng/mL
HAMA	611.8 IU/mL

Controlled studies of potentially interfering exogenous substances performed in EDTA plasma at two PTH levels (70 and150 pg/mL) showed no interference in the LIAISON® N-TACT® PTH Gen II assay.

Drug/Substance	Concentration at which no significant interference (≥ ±10%) was observed.
Acetaminophen	0.2 mg/mL
Acetylsalicylic Acid	0.65 mg/mL
Salicylic Acid	0.6 mg/mL
Ibuprofen	0.5 mg/mL
Alendronate	0.08 mg/mL
Etidronate	1.05 mg/mL
Pamidronate	0.18 mg/mL
Risedronate	0.06 mg/mL
Vitamin D2	240 ng/mL
Vitamin D3	240 ng/mL
Calcitriol	1 ng/mL
Alfacalcidol	2.5 µg/mL
Biotin	1 µg/mL
Calcium Acetate	0.4 mg/mL
Calcium Citrate	0.4 mg/mL
Magnesium Chloride	0.4 mg/mL
Aluminum Sulfate	0.4 mg/mL
Lanthanum Chloride	0.4 mg/mL

Limit of Blank, Limit of Detection and Limit of Quantitation

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined according to CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline June 2012- Second Edition.

The following limits were determined with the LIAISON® N-TACT® PTH Gen II Assay:

LoB	LoD	LoQ
≤ 0.5 pg/mL	1.5 pg/mL	3.0 pg/mL

Stability

Product	Storage Conditions		Claimed stability
Reagent Integral	Open vial	on system	56 days
Calibrators	Open vial - Reconstituted	on system	8 hours
	Open vial - Reconstituted	2-8°C	48 hours
Calibration curve	N/A	N/A	28 days
Controls	Open vial - Reconstituted	Room temp	7 hours
	Open vial - Reconstituted	2-8°C	8 hours
Calibration Verifiers	Open vial - Reconstituted	Room temp	7 hours
	Open vial - Reconstituted	2-8°C	8 hours

Traceability

The LIAISON® N-TACT® PTH Gen II Calibrators, Controls and Calibration Verifiers are traceable to an in-house standard preparation referenced to the WHO International standard, PTH human recombinant, NIBSC 95/646.

Value Assignment

Calibrators

A minimum of 5 vials of each level of calibrator are tested on a minimum of 3 LIAISON® XL Analyzers, in a minimum of 5 assay runs with six replicates per vial resulting in a minimum of 30 individual replicate results per calibrator level for final value assignment.

Controls

A minimum of 10 vials of each level of control are tested on 2 different LIAISON® N-TACT® PTH Gen II assay kit lots on a minimum of 3 LIAISON® XL Analyzers, in a minimum of 5 assay runs with 4 replicates per vial resulting in a minimum of 40 individual replicate results per control level for final value assignment.

Calibration Verifiers

A minimum of 12 vials of each level of calibration verifier are tested on 2 different LIAISON® N-TACT® PTH Gen II assay kit lots on a minimum of 4 LIAISON® XL Analyzers, in a minimum of 6 assay runs with 4 replicates per vial resulting in a minimum of 48 individual replicate results per control level for final value assignment.

13. Conclusion:

The LIAISON® N-TACT® PTH Gen II, LIAISON® N-TACT® PTH Gen II Control Set and the LIAISON® N-TACT® PTH Gen II Calibration Verifiers are substantially equivalent in principle and performance to the Siemens ADVIA® CENTAUR INTACT Parathyroid Hormone (iPTH) Assay, the LIAISON® N-TACT® PTH Control Set and the LIAISON® N-TACT® PTH Calibration Verifiers, respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 8, 2013

DiaSorin Inc.
Ms. Carol A. DePouw
1951 Northwestern Ave.
P.O. Box 285
STILLWATER MN 55082-0285

Re: K132515
Trade/Device Name: LIAISON N-TACT PTH Gen II, LIAISON N-TACT PTH Gen II Control Set, LIAISON N-TACT PTH Gen II Calibration Verifiers
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid hormone test system
Regulatory Class: II
Product Code: CEW, JJX
Dated: October 23, 2013
Received: October 25, 2013

Dear Ms. DePouw:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K132515

Device Name

LIAISON® N-TACT® PTH Gen II
LIAISON® N-TACT® PTH Gen II Control Set
LIAISON® N-TACT® PTH Gen II Calibration Verifiers

Indications for Use *(Describe)*

The LIAISON® N-TACT® PTH Gen II is an *in vitro* chemiluminescent immunoassay (CLIA) intended for the quantitative determination of intact human parathyroid hormone in serum, EDTA and Lithium Heparin plasma samples. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia and hypocalcemia resulting from disorders of calcium metabolism. The test is to be performed on the LIAISON XL analyzer.

The LIAISON® N-TACT® PTH Gen II Control Set is intended for use as assayed quality control samples to monitor the accuracy and precision of the DiaSorin LIAISON® N-TACT® PTH Gen II assay.

The LIAISON® N-TACT® PTH Gen II Calibration Verifiers are assayed quality control materials intended for the quantitative verification of calibration and reportable range of the LIAISON® N-TACT® PTH Gen II assay.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S