K033426

FEB 12 2004

510(k) SUMMARY

SUBMITTED BY: David M. Ikeda
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October 22, 2003

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

NAME OF DEVICE:

Trade Name:	LIAISON® N-tact™ PTH Assay LIAISON® N-tact™ PTH Control Set
Common Names/Descriptions:	Automated chemiluminescent immunoassay for the quantitative determination of human parathyroid hormone (PTH) in serum or plasma.
Classification Name:	Parathyroid hormone test system
PREDICATE DEVICE:	DPC Coat-A-Count® Intact PTH IRMA

INTENDED USE: The LIAISON® N-tact™ PTH Assay is a chemiluminescent immunoassay to be used with the LIAISON® Analyzer for the quantitative determination of intact human parathyroid hormone in serum or EDTA plasma. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia and hypocalcemia resulting from disorders of calcium metabolism. Assay results should be used in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions.

The LIAISON® N-tact™ PTH Control Set is intended for use as an assayed quality control sample to monitor the accuracy and precision of the DiaSorin LIAISON® N-tact™ PTH immunoassay.

DEVICE DESCRIPTION: The method for quantitative determination of PTH is a direct, two site, sandwich type chemiluminescence immunoassay (CLIA). Affinity-purified antibody to the 39-84 amino acid sequence of PTH is coated to the solid phase. The second affinity-purified antibody to the 1-34 region is conjugated to an isoluminol derivative. During the incubation, PTH binds to the solid phase, and is subsequently bound by the isoluminol conjugated antibody. After the incubation, the unbound material is removed with a wash cycle. The starter reagents are then added and a flash chemiluminescent reaction is initiated. The light signal is measured by a photomultiplier as relative light units (RLU) and is proportional to the concentration of PTH present in calibrators, controls, or samples.

TECHNOLOGICAL COMPARISON TO PREDICATE:

Assay / Feature	**DPC Coat-A-Count® PTH Assay***	**LIAISON® N-tact™ PTH Assay**
Analyte	Human Parathyroid Hormone	Human Parathyroid Hormone
Intended Use	FOR *IN VITRO* DIAGNOSTIC USE. Coat-A-Count® Intact PTH IRMA is an immunoradiometric assay designed for the quantitative measurement of intact parathyroid hormone (parathyrin, PTH) in serum. It is intended strictly for *in vitro* diagnostic use as an aid in the differential diagnosis of hypercalcemia and hypocalcemia	FOR *IN VITRO* DIAGNOSTIC USE. The LIAISON® N-tact™ PTH Assay is a chemiluminescent immunoassay to be used with the LIAISON® Analyzer for the quantitative determination of intact human parathyroid hormone in serum or EDTA plasma. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia and hypocalcemia resulting from disorders of calcium metabolism. Assay results should be used in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions.

Antisera	Polyclonal specific for PTH (44-84)	Polyclonal specific for PTH (39-84)
Tracer	^{125}I-labelled polyclonal antibody to PTH (1-34)	Chemiluminescent ABEI labeled polyclonal antibody to PTH (1-34)
Standards	Seven lyophilized serum based controls to be reconstituted in water representing concentrations from 0 to 3000 pg/mL	Stored Master Curve based on 10 points, derived from serum based standards representing concentrations from 2.5 to 2000 pg/mL.
Kit Controls	Two concentrations of lyophilized controls	Two concentrations of lyophilized controls

PERFORMANCE DATA: A summary of performance data is shown below.

Parameter	**Performance Results**
Sensitivity (Analytical)	1.0 pg/mL
Sensitivity (Functional)	2.1 pg/mL
Assay Range	2.5 – 2000.0 pg/mL
Total Precision (%CV)	< 10% in range from 35 – 1289 pg/mL
Recovery (Mean ± SD %)	100.5% ± 7.3%
Linearity (Expected vs. Observed)	y = 0.92x + 4.6; r = 0.98
PTH Fragment Cross-reactivity	1 – 34 < 0.1% 13 – 34 < 0.1% 39 – 68 < 0.1% 39 – 84 < 0.1% 44 – 68 < 0.1% 53 – 84 < 0.1% 7 – 84 90.5%
Endogenous Substance Interferences	No significant interference observed from hemoglobin; <15% interference from triglycerides (800 mg/dL) or bilirubin (15 mg/dL).
Sample Types	Serum or EDTA Plasma
Reference Ranges	Normal: 7.0 – 82.0 pg/mL Hypoparathyroidism: 0.0 – 21.0 pg/mL Hyperparathyroidism: 48.6 – 368 pg/mL

Analytical sensitivity was determined from the assessment of three lots of materials. Analytical sensitivity was defined as the concentration corresponding to the signal obtained at two standard deviations from the mean of the signal of the zero concentration samples. Analytical sensitivity determined by this method was $\leq$ 1.0 pg/mL for all lots. Functional sensitivity, determined as the mean concentration at which the mean imprecision, expressed as %CV, exceeds 20%, was determined from serial dilution to be 2.1 pg/mL. Linearity of dilution was demonstrated using nineteen samples and four lots of materials. The correlation

coefficient of the linear regression of the Expected Concentration vs. Observed Concentration was 0.98. Inter-assay precision, expressed as %CV, was < 10% over a concentration range from 35 – 1290 pg/mL. Recovery was assessed by spiking synthetic PTH at known concentrations into serum samples. Mean percent recovery (± SD) was 100.5% ± 7.3%. Samples subjected to 4 freeze/thaw cycles gave results equivalent to fresh samples (paired *t* test p value of 0.968). No carryover was observed in testing low concentration samples directly after high concentration samples. The LIAISON® method correlated well with the predicate device (r = 0.992), giving equivalent values when evaluated by Student's *t* test (p = 0.172). The reference range established from a population of normal, apparently healthy volunteers (7.0 – 82.0 pg/mL) utilizing the 2.5th to 97.5th percentiles, was very similar to the predicate device (12 – 72 pg/mL). Reference ranges were also determined for subjects with an established diagnosis of either hypoparathroidism or hyperparathyroidsim, 0.0 – 21.0 pg/mL and 48.6 – 368 pg/mL respectively.

CONCLUSIONS:
These data demonstrate the safety and effectiveness of the LIAISON® N-tact™ PTH Assay for its intended *in vitro* diagnostic use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. David M. Ikeda
Manager, Regulatory Affairs & Quality Systems
Diasorin, Inc.
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P.O. Box 285
Stillwater, MN 55082-0285

Re: k033426
Trade/Device Name: Liaison® Control N-tact™ PTH
Liaison® N-tact™ PTH
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid hormone test system
Regulatory Class: Class II
Product Code: CEW; JJX
Dated: January 6, 2004
Received: January 7, 2004

Dear Mr. Ikeda:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K033426

Device Name: LIAISON® Control N-tact™ PTH

Indications for Use:

The LIAISON® Control N-tact™ PTH is intended for use as assayed quality control materials to monitor the accuracy and precision of the LIAISON® N-tact™ PTH immunoassay.

Carol Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use: ✓ OR Over-the-Counter Use: _____

(Per 21 CFR 801.109)

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510(k) Number (if known): K033426

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The LIAISON® N-tact™ PTH is a chemiluminescent immunoassay to be used with the LIAISON® Analyzer for the quantitative determination of intact human parathyroid hormone in serum or EDTA plasma. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia and hypocalcemia resulting from disorders of calcium metabolism. Assay results should be used in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions.

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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