K093498

DEC 14 2009

5.0 510(k) SUMMARY

SUBMITTED BY:

Carol A. DePouw
Regulatory/Clinical Affairs Specialist
DiaSorin Inc.
1951 Northwestern Avenue
P.O. Box 285
Stillwater, MN 55082-0285
Phone (651) 351-5850
Fax (651) 351-5669
Email: carol.depouw@diasorin.com

NAME OF DEVICE:

Trade Name:	LIAISON® N-TACT® PTH Calibration Verifiers
Common Names/Descriptions:	Parathyroid Hormone Assayed Quality Control Materials
Classification Names:	Single (Specified) Analyte Controls (Assayed and Unassayed)
Classification Number:	21 CFR 862.1660
Product Code:	JJX

PREDICATE DEVICES : LIAISON® N-TACT® PTH Control Set Reference K033426

DEVICE DESCRIPTION:

INTENDED USE:

The DiaSorin LIAISON® N-TACT® PTH Calibration Verifiers are assayed quality control materials intended for use in the quantitative verification of calibration and reportable range of the LIAISON® N-TACT® PTH Assay when performed on the LIAISON® Analyzer.

KIT DESCRIPTION:

The LIAISON® N-TACT® PTH Calibration Verifiers consist of four levels. Each vial contains lyophilized pooled human plasma spiked with PTH. The calibration verifiers are reconstituted with 2.0 mL of deionized or distilled water, allowed to sit for 10 minutes, and mixed gently before use.

The calibration verifier set is provided with targeted PTH concentrations of 20, 150, 350 and 1500 pg/mL. The four levels were chosen to incorporate the range of the LIAISON® N-TACT® PTH Assay and to challenge the decision points of clinical importance for PTH.

COMPARISON TO PREDICATE DEVICE:

The following table compares the LIAISON® N-TACT® PTH Calibration Verifiers to LIAISON® N-TACT® PTH Control Set.

Table 4: Table of Similiarities

Characteristic	Predicate Device LIAISON® N-TACT® PTH Control Set K033426	New Device LIAISON® N-TACT® PTH Calibration Verifiers
Intended Use	Assayed quality control samples to monitor the accuracy and precision of the LIAISON® N-TACT® PTH Assay	Assayed quality control samples for use in the quantitative verification of calibration and reportable range of the LIAISON® N-TACT® PTH Assay
Analyte	Parathyroid Hormone	Parathyroid Hormone
Matrix	Pooled human plasma with stabilizers and 0.2% Proclin® 300	Pooled human plasma with stabilizers and 0.2% Proclin® 300
Format	Lyophilized	Lyophilized
Product Storage	2 - 8°C before reconstitution -20°C after reconstitution	2 - 8°C before reconstitution -20°C after reconstitution
Product Handling	Reconstitute with 2 mL deionized or distilled H_2O, allow to dissolve on bench top for 10 minutes, mix thoroughly to ensure complete reconstitution	Reconstitute with 2 mL deionized or distilled H_2O, allow to dissolve on bench top for 10 minutes, mix thoroughly to ensure complete reconstitution
Volume	2.0 mL after reconstitution	2.0 mL after reconstitution
Required Reagent	LIAISON® N-TACT® PTH Assay	LIAISON® N-TACT® PTH Assay
Processing	LIAISON® Analyzer	LIAISON® Analyzer

Table 5: Table of Differences

Characteristic	Predicate Device LIAISON® N-TACT® PTH Control Set K033426	New Device LIAISON® N-TACT® PTH Calibration Verifiers
Levels	Two	Four

CONCLUSION:

The material submitted in this premarket notification is complete and supports the substantial equivalence of the LIAISON® N-TACT® PTH Calibration Verifiers to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

DEC 14 2009

DiaSorin, Inc.
c/o Ms. Carol A. DePouw
Regulatory/Clinical Affairs Specialist
1951 Northwestern Avenue
P.O. Box 285
Stillwater, MN 55082-0285

Re: k093498
Trade Name: Liaison® N-Tact® PTH Calibration Verifiers
Regulation Number: 21 CFR §862.1660
Regulation Name: Assayed Quality Control Materials
Regulatory Class: Class I
Product Codes: JJX
Dated: November 11, 2009
Received: November 12, 2009

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k093498

Device Name: LIAISON® N-TACT® PTH Calibration Verifiers

Indication For Use: The DiaSorin LIAISON® N-TACT® Calibration Verifiers are assayed quality control materials intended for use in the quantitative verification of calibration and reportable range of the LIAISON® N-TACT® PTH Assay when performed on the LIAISON® Analyzer.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k093498