

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

A. 510(k) Number:

k090104

B. Purpose for Submission:

New device

C. Measurand:

Calibration verification materials for Vitamin D assay

D. Type of Test:

Control material

E. Applicant:

Diasorin, Inc.

F. Proprietary and Established Names:

Liaison 25 OH Vitamin D Total Calibration Verifiers

G. Regulatory Information:

21 CFR 862.1660

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

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Diasorin Liaison 25 OH Vitamin D Total Calibration Verifiers are assayed quality control materials intended for *in vitro* diagnostic use in the quantitative verification of calibration and reportable range of the Liaison 25 OH Vitamin

Total Assay when performed on the Liaison Analyzer.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Diasorin Liaison Analyzer

I. Device Description:

The Calibration Verifiers are human serum based, liquid, ready-to-use, four level set of quality control (QC) material, targeted to approximate Vitamin D concentrations of 10, 40, 70 and 120 ng/mL. The Calibration Verifiers are provided in vials with buffer salts and sodium azide (<0.1%). The product is used to verify calibration and reportable range of Liaison 25 OH Vitamin Total Assay when performed on the Liaison Analyzer.

Each serum unit used in the preparation of this material was tested by FDA approved methods and found to be negative for antibodies to HIV 1/2 and HCV and nonreactive for HBsAg. These materials were tested and found negative for HIV-1/2, HCV, HBV, and HBsAg. Because no test method can offer complete assurance that infectious agents are absent, these specimens should be handled and treated as potentially infectious.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Diasorin Liaison 25 OH Vitamin D Total Control Set

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

k071480

3. Comparison with predicate:

Both devices measure the same analyte and are prepared in the same serum based matrix. The new device consists of four levels of analyte with a vial volume of 5.0 mL; the predicate consists of two levels of analyte with a vial volume of 4.0 mL.

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

Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable.

b. *Linearity/assay reportable range:*

Not applicable.

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

The intermediate stock solution of the product is prepared using human serum based matrix and 25 OH Vitamin D stock antigen. The concentration of the intermediate stock solution is traceable to spectrophotometric analysis. For each manufacturing build, the verifiers are built gravimetrically from the intermediate stock. The verifier levels for each manufacturing build are confirmed when run as unknowns using a minimum of two Liaison instruments with a minimum of three cleared 25-OH Vitamin D kits. Multiple data points are used to determine the mean (expected) value. Within and between assay standard deviations and coefficient of variations (CV) are calculated for each set of data. The resulting data are averaged to obtain a representative expected value for each calibration verifier level.

The stability protocols and acceptance criteria for this product were reviewed and found to be acceptable.

d. *Detection limit:*

Not applicable

e. *Analytical specificity:*

Not applicable.

f. *Assay cut-off:*

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable.

b. *Matrix comparison:*

Not applicable.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable.

b. *Clinical specificity:*

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

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

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.