

Indications for Use

510(k) Number k102432:

Device Name: Diazyme 25-hydroxy Vitamin D Assay Kit

Indications for Use:

The Diazyme 25-hydroxy Vitamin D Assay is designed for the quantification of total 25-hydroxy Vitamin D in human serum and plasma. The assay results are to be used in parallel with other clinical data to assess the Vitamin D status of a patient. For *in vitro* diagnostic use only.

The 25-hydroxy Vitamin D Assay Calibrator set is intended for use in the calibration of the Diazyme 25-OH Vitamin D Assay Kit only. For *in vitro* diagnostic use only.

The 25-hydroxy Vitamin D Assay Control kit is intended for use as quality controls for the Diazyme 25-OH Vitamin D Assay kit only. For *in vitro* diagnostic use only.

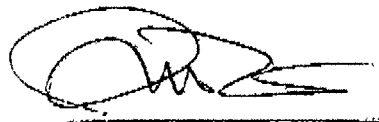
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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