

Indications for Use

510(k) Number: K073488

Device Name: Diazyme Apolipoprotein B Assay

Indications for Use: The Diazyme Apolipoprotein B Assay is intended for the quantitative determination of apolipoprotein B (apo B) in serum. It can be used as an aid for assessing the risk of coronary artery disease. For *in vitro* Diagnostic use.

Calibrator: For calibration of the Diazyme Apolipoprotein B Assay in serum. For *in vitro* Diagnostic Use.

Controls: To monitor the performance of Diazyme Apolipoprotein B Assay in serum. For *in vitro* Diagnostic Use.

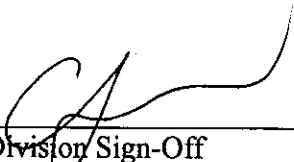
Prescription Use X
(Part 21 CFR 801 Subpart D)

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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