

## Indications for Use

510(k) Number: K072977

Device Name: Diazyme Apolipoprotein A-I Assay

Indications for Use: The Diazyme Apolipoprotein A-I Assay is intended for the *in vitro* quantitative determination of apolipoprotein A-I (apo A-I) 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 A-I Assay in serum. For *in vitro* Diagnostic Use.

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

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K072977

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)