

Indications for Use

510(k) Number (if known): K071971

Device Name: Diazyme Homocysteine 2 Reagent Enzymatic Assay

Indications for Use: Diazyme homocysteine 2 reagent assay is intended for the in vitro quantitative determination of total L-homocysteine in serum or plasma. For in-vitro diagnostic use only. The reagents can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria. Patients who are taking methotrexate, carbamazepine, phenytoin, nitrous oxide, anticonvulsants, or 6-azuridine triacetate, may have higher levels of Homocysteine due to metabolic interference with Homocysteine metabolism.

Device Name: Diazyme Homocysteine Calibrators

Indications for Use: Diazyme homocysteine Calibrators is intended for the in vitro quantitative determination of total L-homocysteine in serum or plasma. 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)

Carol C. Benson

on Sign-Off

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Evaluation and Safety

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