

APR -2 1997

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MEDICAL ANALYSIS SYSTEMS, INC.

510(k) Notification • March 14, 1997

CARDIOIMMUNE Cardiac Marker Control, Levels 1, 2 and 3

510(k) SUBMISSION

Summary:

CARDIOIMMUNE Cardiac Marker Control, is substantially equivalent to the existing Liquichek™ Cardiac Markers Control , (K961828) currently in commercial distribution by BIO-RAD.

Medical Analysis Systems **CARDIOIMMUNE Cardiac Marker Control, Levels 1, 2 and 3** are ready-to-use liquid stable assayed control sera suitable for monitoring test procedures used in cardiac marker determinations. The controls are prepared from a human serum matrix with the addition of various constituents. Preservatives and stabilizers are added to maintain product integrity. The liquid matrix eliminates causes of vial to vial variability and, when handled as directed, provides consistency in day-to-day testing.

The controls are stable for 36 months from date of manufacture when stored unopened at -20°C. Unopened vials are stable for 60 days when stored at 2 - 8°C. Opened vials of control are stable for 30 days when stored tightly capped at 2 - 8°C.

Product Code: **75JJT**

