

### Indication for Use

510(k) Number (if known): k082001

Device Name: Diazyme Liquid Stable Enzymatic Lithium Assay

Indication For Use: Diazyme Liquid Enzymatic Assay Kit is for quantitative *in vitro* determination of Lithium in human serum. Measurements of Lithium are carried out essentially to ensure that proper drug dosage is administered in the treatment of patient suffering from bipolar disorder and to avoid toxicity.

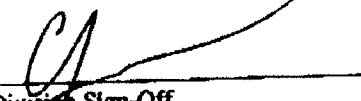
Prescription Use X  
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use \_\_\_\_\_  
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

  
Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

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