

FDA INDICATIONS FOR USE FORM

510(k) Number (if known): K033360

Device Name: Diazyme Lithium Enzymatic Assay Kit

Indications for Use:

Diazyme Lithium 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use *f*

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Carol Benson
Division Sign-Off

**Office of In Vitro Diagnostic Device
Evaluation and Safety**

510(k) K033360