

### Indications for Use

510(k) Number (if known): K070734

Device Name: Diazyme Direct Enzymatic HbA1c Assay

Indications for Use: Diazyme Direct Enzymatic Hemoglobin A1c (glycated hemoglobin A1c; A1c; HbA1c) reagents are intended for use in the quantitative determination of stable HbA1c in human whole blood samples. Measurement of hemoglobin A1c is a valuable indicator for long-term diabetic control. For *in-vitro* diagnostic use only.

Prescription Use  AND/OR Over-The-Counter Use   
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson  
Director Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

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