Indications for Use

510(k) Number (if known): 2070734

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 \(\checkmark\) AND/OR Over-The-Counter Use

(Please do not write below this line-continue on another page if needed)

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

[Signature]

Office of In Vitro Diagnostic Device Evaluation and Safety

Page 1 of 1