

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY ONLY TEMPLATE**

**A. 510(k) Number:**

k080618

**B. Purpose for Submission:**

Notification of intent to manufacture and market a new device for the determination of Fructosamine, Glucose, and Hemoglobin A1c (HgbA1c).

**C. Measurand:**

Fructosamine, Glucose, HgbA1C

**D. Type of Test:**

Fructosamine, Glucose – Colorimetric  
HgbA1c – latex turbidometric immunoassay

**E. Applicant:**

Current applicant JAS Diagnostics (Referenced Pointe Scientific k993590, k970781, and k031539).

**F. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**G. Conclusion:**

The submitted information in this premarket notification is entirely by reference to Pointe Scientific devices cleared under k993590, k970781, and k031539. A substantial equivalence decision is based on previous clearance of those files.