

**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.