510(k) Summary

Submitter: Data Innovations
Contact: Katharine Laddison, Quality, Regulatory and Documentation Manager
Address: 120 Kimball Avenue, Suite 100, South Burlington, VT 05403
Phone number: 802-264-3420
Date: December 11, 2006

Device: Instrument Manager
Predicate Device 1: Cerner PathNet
Predicate Device 2: IDM Surround

Device Description and Intended Use

Instrument Manager is a software package intended to be used by trained laboratory personnel in a blood-banking environment as an aid in interfacing and managing data between blood bank automated instruments and Blood Establishment Computer Software (BECS).

Description and Conclusions of Testing

Instrument Manager version 8.05.01.10 was designed, tested and validated according to our internal design control and testing processes. See *Appendix D* for detailed testing summaries.

This testing included a full, independent validation of the software. It also included user-site testing, which provided testing under simulated use conditions.

Anomalies that were discovered during testing were either fixed and re-tested, or deemed to have no impact on patient safety or device effectiveness. See *Tab 13* for details on outstanding anomalies of the software.

A review of our testing satisfied DI requirements for safety, effectiveness and fitness for use.