DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

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Public Health Service
Memorandum

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Date: January 30, 2003

From: Linda Weir
Division of Blood Applications
HFM-390

To: File BK020058

Subject: **SE BK020058**

1. I reviewed the November 07, 2002 submission for Fifth Dimension's Logic, version 1.0 and recommend that a determination of substantial equivalence be made. The submission was an abbreviated 510(k) and consisted of two volumes. Although the cover letter stated that the submission was an abbreviated 510(k) the firm submitted data appropriate for a special 510(k). The additional information was requested via telecon, was received by CBER and the submission was reviewed as an abbreviated.

2. The intended use is stated to be:

   - Receive unit, container and shipment information through an interface from collection facility data system.
   - Generate shipping documentation.
   - Specify shipping statements, e.g., required testing statements as required by the fractionator to receive shipments for processing
   - Format and generate container labels for facility code and container ID
   - Create and report unit, container and shipment discrepancies
   - Create and follow the status of observations (e.g., post donation information) to resolution.
   - Transfer pallets and containers between storage locations within a facility
   - Create and send shipments to facilities
   - Receive shipments from facilities and verify containers received
   - Manually record pool and manufactured lot information
   - Secure internal security controls for application and database via the assignment and configuration of security roles and the creation of staff members.
   - Secure external security controls (i.e., internet) via secure HTTPS protocols, IP address filters, server certificates, and firewalls

3. Note that the only functions that required premarket notification via 510(k) were those concerning the recall and final disposition of blood products and the submission was reviewed for these functions.

4. The predicate device is stated to be Fifth Dimension's System for Plasma Identification (SPI) version 1.0, BK020020.

5. The operating system is Windows 2000 and the database is Oracle 9i. The application uses HTTPS protocol exchange data through the Internet and uses a Java Applet running on the client workstation to display the application.

6. The following were reviewed and deemed acceptable:

   - Statement of the use of a special control in support of an abbreviated 510(k)
   - Predication device comparison table
   - Trace matrix
   - Functional specifications
   - Detailed design specifications
   - Architectural diagram
   - Hazard analysis
   - Limitations
   - Error messages
   - Labeling
   - User manual
   - Financial Disclosure Statement