# 510(k) Summary of Safety and Effectiveness

**Substantially Equivalent 510(k) Device Information:**
Applicant: Fifth Dimension Information Systems, A HAEMONETICS® Company
Product: LOGIC, version 2.0.0
Date: April 28, 2004

**Summary of Safety and Effectiveness**

| | |
|---|---|
| **Classification Name:** | Unclassified, Device Code MMH |
| **Product Trade Name:** | LOGIC version 2.0.0 |
| **Common Name:** | Blood Establishment Software |

**Predicate Device:**
The LOGIC 2.0.0 system is substantially equivalent to its previously submitted version, LOGIC 1.0 (cleared via BK020058). A detailed description of the comparison of the two versions can be found in LOGIC 2.0.0 Substantial Equivalence (LOGIC-FDA-0020).

**Device Description:**
Like the predicate device, LOGIC is a software application used in the support of daily operations of product logistics and observations management.

The features of LOGIC are as summarized:

- Receive unit, sample, container (e.g. carton), pallet and shipment information through an interface from collection facility data systems.
- Generate shipping documentation, e.g. packing lists and bill of lading.
- Specify shipping statements, e.g. required testing statements as required by the fractionator to receive shipments for processing.
- Format and generate container and pallet labels.
- Create and report unit, sample, container and shipment discrepancies.
- Create and follow the status of observations (e.g. post donation information) to resolution.
- Create and issue facility alerts.
- Transfer pallets and containers between storage locations within a facility.
- Place and manage orders for products.
- Create and apply certifications.

- Create, moderate and send shipments to facilities (e.g. fractionators, warehouses and disposal).
- Receive shipments from facilities and verify containers and/or pallets received.
- Manually record pool and manufactured lot information.
- Create and administer donors.
- Create and manage deferrals against donors.
- Create attribute profile(s) (e.g. test result matching) and configure the profile to perform pre-defined action(s) (e.g. create discrepancy) within the system when that profile matches the attribute(s) recorded against a unit.
- Create and utilize transports for shipments.
- Secure internal security controls for application and database via the assignment and configuration of security roles and the creation of staff members (users) who are authorized to access LOGIC.
- Secure external security controls (i.e. internet) via secure HTTPS protocols, IP address filters, server certificates, and firewalls.

**Intended Use:**
The intended use of LOGIC is to organize and control the movement of units between facilities (e.g. collection sites, warehouses, and fractionators). Logic communicates observations (e.g. post donation information), status, and recalls between collection, warehouse, and fractionation facilities. LOGIC has been in production since July 08, 2003.

**Technological Characteristics:**
The LOGIC 2.0.0 system is technologically similar to the predicate device. It utilizes the same software architecture, and is operated on the same database as LOGIC 1.0.

**Summary of Safety and Efficacy:**
LOGIC version 2.0.0 has been validated. A hazard analysis has been developed and all hazards identified have been mitigated. Like the predicate device, LOGIC is safe and effective for it's intended use.