

## Section 6 510(k) Summary

### 6.1 Submitter's Contact Information

GE Medical Systems Information Technologies, Inc.  
8200 West Tower Avenue  
Milwaukee, WI 53223

Questions/Requests for Additional Information should be addressed to:

Nancy Jensen  
Senior Manager Regulatory Affairs  
GE Medical Systems Information Technologies, Inc.  
540 Northwest Highway  
Barrington, IL 60010  
Telephone: (847) 277-5264  
Email: Nancy.Jensen@med.ge.com

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### 6.2 Name of Device

**Proprietary name:** Centricity® Ultra Laboratory Transfusion Medicine, version 4.0

**Common name:** Blood Establishment Computer Software

### 6.3 Identification of Legally Marketed Predicate Devices

The GE Medical Systems, Information Technologies, Inc. Transfusion Medicine software is substantially equivalent to the following:

#### 6.3.1 Predicate Device:

**Manufacturer:** Cerner Corporation

**Common Name:** Blood Bank System

**Trade Name:** PathNet Blood Bank Transfusion

**510(k) Number:** BK950053 (7/16/97)

#### 6.3.2 Device Description

The Centricity® Ultra Laboratory Transfusion Medicine software application supports the major functions of a hospital transfusion department, including product receipt; inventory processing, patient resulting and reporting, and maintenance of transfusion recipient information. In addition, Centricity® Ultra Laboratory Transfusion Medicine was designed to support the blood bank technologist by assisting in crossmatching activities. However, final decisions regarding compatibility and distribution of units are made by the blood bank technologist.

### 6.3.3 Intended Use

The Centricity® Ultra Laboratory Transfusion Medicine application is intended for use in blood banking facilities. The application receives and stores data regarding the processing, testing, storage and distribution of blood and other non-blood component units. The Centricity® Ultra Laboratory Transfusion Medicine software application supports the major functions of a blood bank department, including product receipt, inventory processing, patient resulting and reporting, electronic crossmatch/electronic issue, and maintenance of transfusion recipient information. The Centricity® Ultra Laboratory Transfusion Medicine application was designed to support the blood bank technologist by tracking the testing of units and patients. The application compares compatibility between patient(s) and unit based on patient ABO/Rh/antibodies in comparison to the unit values for units that are to be dispensed to a patient. However, final decisions regarding compatibility and distribution of units are made by the blood bank technologist.

### 6.3.4 Comparison of Technological Characteristics

<b>Centricity® Ultra Laboratory Transfusion Medicine System Other Technological Characteristics</b>	<b>Cerner Corporation PathNet Other Technological Characteristics</b>
Application Language – Unify Vision version 6.0	Application Language – COBOL, C, CCL
Database –Unify Dataserver version 7.2	Database – Person-centric relational database
User Interface – Microsoft Windows 2000 SP4	User Interface – Windows 95, Windows NT and terminals
Operating System – IBM AIX version 5.1	Open VMS, AIX

### 6.3.5 Description and Conclusions of Testing

The Centricity® Ultra Laboratory Transfusion Medicine 4.0 software was developed and validated using established procedures for software development. As such, it is anticipated that this system is as safe and effective as, and will perform as well as or better than the identified predicate devices when utilized within its intended use, as verified by the clinical and non-clinical testing that was performed.

#### 6.3.5.1 Non-Clinical Testing

The Centricity® Ultra Laboratory Transfusion Medicine 4.0 software was developed and validated using established procedures for software development. As such, it is anticipated that this system is as safe and effective, and will perform as well as the identified predicate devices when utilized within its intended use, as demonstrated by the clinical and non-clinical testing performed.

Unit, integration and system testing were performed internally by GE Medical Systems, Information Technologies, Inc personnel. Unit testing focused on structural tests constructed by analysis of portions of the code related to safety critical functions and defining tests to verify each identified line of code executed properly. Integration testing focused on integration of modules including data integrity and flow across modules. System testing focused on ensuring that the application met the requirements set forth in the requirements document(s).

The assessment of this testing verified that the GE Medical Systems, Information Technologies software, Version 4.0 design input requirements were met.

#### **6.3.5.2**

##### **Clinical Testing**

Centricity® Ultra Laboratory Transfusion Medicine 4.0 software beta testing was performed in a user environment against a user database. The Centricity® Ultra Laboratory Transfusion Medicine 4.0 beta test was the basis for executing this client testing. The assessment of this testing verified that the GE Medical Systems, Information Technologies, Inc. software, Version 4.0 met the required specifications and functioned as intended.

In summary, GE Medical System, Information Technologies, Inc. ensured that all safety critical items were thoroughly tested and demonstrated that all methods of control for intended use and general implementation hazards were satisfactorily tested.