

**510(k) SUMMARY**  
**PREPARED OCTOBER 24, 2002**

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**MANUFACTURER SUBMITTING 510(k) NOTIFICATION:**

Hemocare Product Center  
Mediware Information Systems, Inc.  
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**CONTACT PERSON:**

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**DEVICE NAME:**

Proprietary Name: Hemocare LifeLine, Release 1.0  
Common Name: HCLL  
Classification Name: Software, Blood-Bank, Stand Alone Products

**PREDICATE DEVICE:**

Cerner PathNet Blood Bank Transfusion, version 306

**DEVICE DESCRIPTION:**

The Hemocare LifeLine System is a stand-alone blood bank software device that aids in the management of single, multi-site, or centralized transfusion services.

**INTENDED USE:**

The Hemocare LifeLine (HCLL) is used to address all phases of transfusion services activities. It encompasses functionality that includes:

- Maintaining a reliable patient database,
- Manually and electronically registering, admitting and transferring patients,
- Receiving patient and unit specimens,
- Manually and electronically receiving patient orders,
- Testing patient and unit specimens,
- Performing electronic crossmatch,
- Issuing blood products under normal and emergency conditions
- Receiving outside inventory,

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- Manipulating and labeling blood products, and
- Shipping of specimens, reagents, derivatives and blood products.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE DEVICE:**

Both products utilize a graphical user interface. The systems are fully scalable using an enterprise based client-server architecture and a relational database.

**SAFETY AND EFFECTIVENESS DATA:**

The Hemocare LifeLine System was developed using an established procedure for software development.

The assessment of the nonclinical (alpha) testing is that the HemocareLifeLine System design input requirements had been met. The design validation process demonstrated that the Hemocare LifeLine system meets the requirements for the intended use.

Clinical/user site (beta) testing was conducted to validate the Hemocare LifeLine software. Testing was conducted at three different clinical environments: core lab, medium volume facility, and low volume facility. The results of the beta testing demonstrated that the Hemocare LifeLine software met the required specifications and functioned as expected.

**CONCLUSION:**

The conclusions drawn for the nonclinical and clinical tests demonstrate Hemocare LifeLine, Release 1.0, is substantially equivalent to the predicate device when utilized within its intended use.