

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

**Public Health Service
Memorandum**

Date: February 13, 2003
From: Linda Weir 
Division of Blood Applications
HFM-390
To: File BK020046
Subject: SE BK020046

I reviewed the October 25, 2002 submission and the January 13, 2003 response letter for Mediware's Hemocare LifeLine, Version 1.0.

The intended use is stated to be software to address all phases of transfusion services activities. It encompasses the following functionality:

- Maintaining a reliable patient database
- Manually and electronically registering, admitting and transferring patients
- Receiving patient and unit specimens
- Testing patient and unit specimens
- Performing electronic crossmatch
- Issuing blood products under normal and emergency conditions
- Receiving outside inventory
- Manipulating and labeling blood products
- Shipping of specimens, reagents, derivatives and blood product

Hemocare Lifeline operates on a client server platform. Users are typically connected to the Hemocare Lifeline system through a network.. Mediware does not provide direct support for customer networks.

Mediware claims substantial equivalence to BK990007, Cerner HNA Millennium PathNet Blood Bank Transfusion (Pathnet), BK000040, Soft Computer Consultants, SoftBank, version 21.1 and BK010052, LifeTrak/Lab, version 2.03.

The following areas were reviewed and deemed acceptable:

- Statement of the use of a special control in support of an abbreviated 510(k)
- Predicate device comparison table
- Trace matrix
- Functional specifications
- Detailed design specifications
- Architectural diagram
- Hazard analysis

- Limitations
- Labeling
- Financial Disclosure Statement
- Blood product labels