VII. 510(k) Summary
(Per 807.92 510(K) content instructions)

A. Summary

(1) Submitter's name, address, telephone number, a contact person and date summary was prepared:

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August 27, 2004

(2) Name(s) of device:

Proprietary/Trade Name: wBloodCare™, Version 1.0
Common Name: Transfusion Service Information System
Classification Name: Unclassified 81 MMH, Software, Blood Bank Stand-a-lone Products

(3) Legally Marketed Predicate Devices to which submitter claims substantial equivalence:

The wBloodCare application software functionality is claimed to be substantially equivalent to the following predicate devices:

Manufacturer	Product	510(k) Number	Date of 510(k) Approval
Psyche Systems Corp Ten Laurel Avenue Wellesley, MA 02481	System Blood Bank (SBB) Software Ver. 3.0s	BK010017	09/24/2001
Wyndgate Technologies 111212 Sun Center Drive Suite C Rancho Cordova, CA 95670	SafeTrace TX,	BK980023	01/29/1999

(4) Description of device:

The Care Fusion wBloodCare software device is a software application that operates via the client server environment accessed via a Pocket PC Terminal (PPT) with an

integrated barcode scanner. The device is equivalent functionality to that provided by desktop or laptop devices with attached barcode to support bar code scan and read technology to aid in management of transfusion services described further in the intended use. Unauthorized access to patient information is protected as it is communicated via the network as it utilizes the security encryption standard of 128 bit 3DES. Users are also required to authenticate via a user ID and passcode to obtain access to the device.

(5) Statement of intended use:

wBloodCare is a comprehensive computer software application that manages transfusion service activities. It maintains a transfusion history.

- Tracks patient identification information
- Captures orders for patient blood product administration(s)
- Tracks product delivery/disposition related to release of product
- Assists in determination of the suitability of blood products.
- Records transfusion activities and results.

This device is not intended to diagnose, treat, prevent, cure or mitigate any disease or conditions. Nor is it intended for any particular patient disease or condition population.

There are no differences in performances of intended use that would affect the safety and effectiveness of the device as compared to the predicates.

(6) Comparison of Technological Characteristics to Predicate Devices:

Predicate devices as described in their technological characteristics utilize an attached barcode scanner as an input method via desktop/laptop devices. WBloodCare uses an equivalent software environment accessible from a Pocket PC Terminal (PPT) with an integrated scanner to support equivalent functionality. Predicate devices complete identification match and assignment of blood product to the patient within the blood bank. wBloodCare utilizes this same information at the bedside to confirm data prior to actual product administration. Both predicate devices and wBloodCare are fully scaleable using enterprise client-server architecture and a relational database.

B. Performance data

(1) Non-clinical System Testing

The end-to-end regression test is a final system check to ensure that wBloodCare, has met the intended use and fulfills all critical safety requirements.
The full system test took place in the test lab of Care Fusion. A hospital information system (Cache 5.0) was set up in-house to test the interface engine functionality of receiving and parsing the HL7 interface messages.

This full system test utilized a comprehensive set of system test cases which were executed these cover all functional requirements and integration testing. Each test case is traceable to one or more functional requirements and each functional requirement is traceable to one or more test cases. The summary of the results of these test cases are included in section XII.B.

Prior to the completion of system testing all fail occurrences were resolved – either corrected and retested or scheduled for future correction as shown in section XIII. All safety critical issues which were within the scope of the wBloodCare functional software requirements were corrected.

(2) Clinical –Beta Testing

The objective of the clinical site acceptance (beta) test is to perform validation and verification testing of all aspects of wBloodCare, in a user production test environment prior to the final release of the software. The beta testing promotes the identification of errors, inconsistencies and deviations in wBloodCare. As issues arose these were tracked using internal bug tracking database through issue resolution and software correction.

Care Fusion arranged for the clinical site acceptance (beta) testing to be carried out in the Veterans Administration Hospital located in Washington D.C. (VADC). VADC has a hospital information system VISTA that processes patient registration and transfusion orders that Care Fusion could utilize in testing of the interface engine and the rest of the wBloodCare, application.

The results of this testing are included in sections XII and XIII. All fail occurrences were corrected or scheduled for future correction. All issues related to the safety critical functionality were corrected. Retesting of each corrected failure yielded pass situations.

(3) Conclusions of Non-clinical and Clinical testing

The Care Fusion wBloodCare system was developed using established procedures for software development. The internal/nonclinical design validation and (alpha) testing process demonstrated that the wBloodCare system met the requirements for its intended use.

Clinical/user site beta testing of wBloodCare was performed in a hospital production test environment. It was demonstrated that wBloodCare software met the required specifications and functioned as expected.

The following table summarizes the test results at the clinical and system level:

Test Activity	Clinical Test	System Test	Total
Test Cases executed	18	18	36
Initial Test Case Failures	3 (1 of which N/A for retest)	2 (Both N/A for retest)	5
Test Case Failure on re-test	0	N/A	2 (both of which are outside the scope of wBloodCare application)

The full system (regression) test confirms that Care Fusion has addressed all safety critical errors discovered from the site acceptance test and all other internal tests. Care Fusion believes that wBloodCare has met the expectation for a high quality product, and is functioning as designed. Care Fusion believes that wBloodCare will help ensure the safety, quality and identity of blood products and patient safety.

The conclusions drawn from the comparison of statement functionality of predicate devices and software tests demonstrate that wBloodCare is substantially equivalent to predicate devices when utilized as intended.