

**510(k) Summary**  
Prepared September 12, 2003

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

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**DEVICE NAME:**

Proprietary Name: WebLab Online Laboratory System, version 2.0  
Common Name: WebLab  
Classification Name: Software, blood bank, stand alone

**PREDICATE DEVICE:**

Abbott DMS Version 3.0.2 System (BK950032)

**DEVICE DESCRIPTION:**

The WebLab system is a device which transfers a laboratory test results (Lab Results) file from a blood testing laboratory, so that it can be used by a blood bank software program. WebLab uses the industry standard FTP protocol to transfer the lab results file.

- The test units are sequenced into WebLab where the information is saved in the SQL Server Database.
- The sequenced information is then sent to the Testing Laboratory.
- The test results are transferred from the Testing Laboratory to the Blood Bank System using the FTP protocol.
- The WebLab Archives the test results file for audit trail.
- The WebLab sends email notification about the success or failure of the FTP process.
- The WebLab provides reports such as Not tested, Quarantine, All test results and exception report.

**INTENDED USE:**

The WebLab system is a computerized system intended to be used by trained personnel as an aid in the transfer of Lab Results from a blood testing laboratory, so that it can be used by a blood bank software program. The WebLab system also provides the following information management tools: an electronic storage area for sample data, sequences the samples to be tested, archives the Lab Results file, sends email notifications, provides secured login, provides reports. The

functionality is designed to allow for increased oversight via an audit trail, as well as through the use of warning messages and integrity checks.

Note: The WebLab system is not designed for, nor is it intended to in anyway manipulate Lab Results transferred from the blood testing laboratory.

**COMPARISON OF CHARACTERISTICS OF WEBLAB 2.0 TO ABBOTT DMS VERSION 3.0.2, (BK950032):**

<b>AREAS OF COMPARISON</b>	<b>SIMILARITIES</b>	<b>DIFFERENCES</b>
1. Create Sequence	DMS and WebLab are designed to Sequence the samples to be tested.	
2. Transfer Laboratory Test Results	DMS and WebLab are used by trained personnel to transfer the Laboratory test results data to a host computer	DMS uses Asynchronous transfer. The WebLab uses the industry standard FTP protocol.
3. Input	The DMS and the WebLab systems utilize a keyboard and bar code scanner.	
4. Output	The DMS and the WebLab systems use CRT's and Printers for output.	WebLab sends email notifications when the FTP is successful or fails.
5. Safety Characters	The DMS and WebLab systems alert users when unusual conditions occur. DMS and WebLab use bar code scanners to reduce/eliminate clerical errors.	WebLab archives the Lab Results file for audit trail.

**SAFETY AND EFFECTIVENESS DATA:**

This system has been tested with The Blood Center New Orleans for the safety and effectiveness of data. The following tests were performed:

1. Transfer of Specific Test Results.
2. Maximum Stress Testing (minimum 500 donor samples)
3. Minimum Stress Testing
4. File Overwrite

**Conclusions drawn from the System Testing**

The test results data provided reasonable assurance that the WebLab device is safe and effective when used in accordance with the device intended use.