



## **510(k) Summary**

**PREPARED** May 19, 2006; Revised 6/23/06

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

Talisman Ltd.  
421 F Church Street NE  
Vienna, VA 22180  
703 242-4200 voice  
703 242-4282 fax

### **CONTACT PERSON**

Philip S. Abrams, PhD  
philip.abrams@talmed.com

### **DEVICE NAME**

Proprietary Name: Talisman Phlebotomy System Release 1.0  
Common Name: Phlebotomy computer software  
Classification Name: Software, blood bank, stand alone products. The product code is 81MMH

### **PREDICATE DEVICE**

Donor-ID version 2.5, 510(k) Number: BK030049

### **DEVICE DESCRIPTION**

The Talisman Phlebotomy System™ (TPS) is a software system for management of donors during the phlebotomy process. TPS is a web application used by phlebotomists with hand held computers that communicate with the server wirelessly. By using TPS, a blood center can track donors throughout the phlebotomy process. The system assures that all relevant data are collected and are within bounds, thereby minimizing or eliminating related errors.

### **INTENDED USE**

Indications for use for the Talisman Phlebotomy System are the need to reduce or eliminate errors and omissions in the phlebotomy phase of the blood donation process.

The Talisman Phlebotomy System (TPS) is a computer system to be used by trained blood center staff to manage donors during the phlebotomy process and to collect and record phlebotomy data. These data can be exported in machine-readable form. Staff members use wireless hand held computers to collect data and to communicate in real time to the system as it runs on a server. TPS requires that all required data be entered and be within bounds and minimizes the need for character data entry by using selection from lists and bar code scanning.

The purpose of the system is to improve consistency of the blood donation process and reduce or eliminate human errors and omissions, including but not limited to completeness, data transposition, key entry, and communication errors.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE DEVICE**

<b>Characteristic</b>	<b>Talisman Phlebotomy System</b>	<b>Predicate Device</b>
Networking	Networked or standalone	Can be installed on an existing PC network.
Server Platform	Personal computers	Personal computers
Server operating system	Microsoft Windows XP, Windows 2000 Server or Windows Server 2003	Microsoft Windows 2000 Terminal Server
Phlebotomist client computer	Hand held computer	Portable data terminal
Client computer operating system	Windows Mobile 5.0 (Microsoft)	Pocket PC (Microsoft)
Database	Microsoft Access	Microsoft Access

Discussion: The technological characteristics of TPS are either identical or similar to those of the predicate device, and do not raise new types of safety or effectiveness questions. The descriptive information of the two devices demonstrates equivalence.

**SAFETY AND EFFECTIVENESS DATA**

The Talisman Phlebotomy System was developed using established procedures for software development that include design reviews and software testing. Developers perform both unit tests and system tests on their code. Completed systems are tested internally by non-development staff using formal test procedures and defined scenarios and scripts.

*Non-clinical System Testing:*

The system was tested with a complete battery of validation and verification tests, the results of which are contained in section 16.8 (Tab 22) of the 510(k) application. No critical failures were detected.

*Clinical System Testing (Beta testing):*

The purpose of the beta test is to perform user validation and verification testing of the Talisman Phlebotomy System in a user environment prior to the final release of the software. The beta tests were conducted by Mississippi Valley Regional Blood Center to identify any errors, inconsistencies or deviations in the system prior to final release. No critical failures were detected during beta testing. Beta test records are contained in section 16.9 (Tab 23) of the 510(k) application.

**CONCLUSION**

Based on a comparison of the Talisman Phlebotomy System and the predicate device, TPS is substantially equivalent to the predicate. Based on the outcome of non-clinical tests and of

clinical (beta) testing, the system has met the expectations of high product quality and is fit for its intended use.