510(k) Summary

BK: 060014
PowerBANK Enterprise Edition, Version 1.0

Applicant: **MOSUM Technology (INDIA) Pvt. Ltd.**

Ownership Information:
MOSUM is now owned by: Eclipsys Corporation.
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A2. Device Name:

Common Name: Transfusion Service Management Information System
Trade / Proprietary Name: PowerBANK Enterprise Edition Version 1.0
Classification Name: Stand Alone Blood Bank Software, Product Code 81 MMH

A3. Substantial Equivalence:

PowerBANK is substantially equivalent in its intended use and features to Safe Trace TX BK 980023, SMS Blood Bank Transfusion System, BK960036, and Softbank II, BK96033.

PowerBANK Transfusion Intended Use	Safe Trace TX BK 980023 Intended Use
A comprehensive computer software package that manages the information system needs of a transfusion service. PowerBANK maintains a complete test and transfusing history for a patient and comprehensive tracking of donor products from receipt to final disposition. The system also can provide the facility for serologic and electronic cross matching.	A comprehensive computer software package that manages the information system needs of a transfusion service. Safe Trace maintains a complete test and transfusing history for a patient and comprehensive tracking of donor products from receipt to final disposition.

Manage and maintain inventory of blood products	Manage and maintain inventory of blood products
Track patient identification information	Track patient identification information
Provide patient information	Manage patient visits and specimens
Process orders for patient test and blood products	Process orders for patient test and blood products
Maintain final product disposition information	Track product disposition
Provide information for the determination of the suitability of released products	Assist in the determination of the suitability of released products
Record transfusion results	Record transfusion results
PowerBANK Transfusion Intended Use	**SMS Blood bank Transfusion System BK 960036**
Produce patient demographics	Patient Information, Product information, test results, Transactions histories, reports
PowerBANK Transfusion Intended Use	**Softbank 11, BK96033**
Support multi site processing	Provides multi-facility management and reporting

Function	PowerBANK	SafeTrace Tx
Overview	Tracks blood bank products from receipt of the product to its final disposition. This includes entering the product, into inventory, manufacturing components, modifying, pooling, cross matching, issuing, transfusing, and shipping to another institute or returned to the supplier.	Tracks blood bank products from receipt to final disposition, from entering products into inventory through modifying, pooling, crossmatching, dispensing, transfusing to a patient, returning and shipping to another institution or back to the supplier.
Inventory	Includes receiving product Transferring product, shipping, managing product records, linking products to recipients, manage and reconcile the product inventory	Contains the major functions needed to receive, transfer and ship products, review and update product records, and link products with recipients, manage and reconcile product inventory

Patient Order	Contains the major functions that management the registration of a patient; maintain patient records, manage specimens, help to manage placement and tracking of orders,, entry and interpretation of patient and product test results, the selection, allocation, processing and testing of products, including crossmatch, component modification, component pooling, component division, product issue and product return,.	Contains the major functions that management the registration of a patient; maintain patient records, manage specimens, help to manage placement and tracking of orders,, entry and interpretation of patient and product test results, the selection, allocation, processing and testing of products, including crossmatch, component modification, component pooling, component division, product issue and product return
Establishing Operating parameters/rules and administration	PowerBANK utilizes its *Wizard* feature to set security, authorizations, and processing rules. This allows the user with authorization, to build tables and can provide a hard copy listing of the processing rules established by the user. It allows for the maintenance of tests, products, services, and providers.	Allows user with security authorization to add, update, or outdate data. Provides functionality to build user defined tables. Provided hardcopy listing of each table and contents. Contains administrative functions for the maintenance of tests, products services and providers.
Security	Maintains user ID and password combinations. Manages and restricts access to system. Maintains login histories and provides stores and provides user security /rights information.	Maintains users ID and password combinations. Manages access to system. Maintains login histories. Repository for all user security profiles across all facilities.

PowerBANK Environment	SafeTrace TX
Server: Dual CPU Pentium 4.2+GHz 2GB RAM SCSI Raid array with 250 GB HDD 1000Mbit Ethernet NIC CD-ROM UPS Tape Drive	Operates on NT server version 3.51 or higher
Application Language – Clarion 5.5b	Application Language – Inprise Delphi
User Interface – Windows 2000 Professional	User Interface – Windows 95 and Windows
Architecture-Highly Scaleable, Multi-tier Client Server	Architecture-Highly scaleable, Multi-Tier client server.
Platforms – Open Industry Standard	Platforms – Open Industry Standard

PowerBANK Life Cycle	Safe Trace Life Cycle
Project Feasibility	Project Feasibility
Context Level Software Requirements	Requirements
System Requirements Specifications	Requirements
Design	Design
Development	Development
Documentation	Documentation
Validation / Test	Validation / Test
Maintenance	Maintenance

A4. Device Description:

Overview
PowerBANK is a comprehensive software package that helps manage the information system needs of a transfusion service. PowerBANK is designed to help meet the needs of both centralized and standalone transfusion services.

PowerBANK maintains test and transfusion history for a patient. Each function has been designed with patient safety as the highest priority.

The system has been tested and validated and is part 11 compliant.

Security
PowerBANK security features ensure that the data entry and access are limited to authorized individuals.

A login and ID is necessary. An administrator grants rights

Audit
PowerBANK provides a complete range of audit capabilities

Database, Hardware and Operating Systems:
PowerBANK has been designed to operate on Microsoft Windows 2000 or 2003 Server. It operates on Pervasive SQL 8 server.

PowerBANK Client workstations require Windows 2000 Professional with Pervasive SQL 8 Client.

Performance Characteristics:
The key performance characteristics are: Product Quality, Maintainability, System reliability, and System Speed and response times.

A5. Statement of Intended Use:
A comprehensive computer software package that manages the information system needs of a transfusion service. PowerBANK maintains a complete test and transfusing history for a patient and comprehensive tracking of donor products from receipt to final disposition. The system also can provide the facility for serologic and electronic cross matching.

- Manage and maintain inventory of blood products
- Track patient identification information
- Provide patient information
- Process orders for patient test and blood products
- Maintain final product disposition information
- Provide information for the determination of the suitability of released products
- Record transfusion results

PowerBANK maintains a complete test and transfusion history for a patient and comprehensive tracking of donor products from receipt to final disposition.

The Intended Use, Features, OS / Database / Hardware Environment, other technological Characteristics and Life-cycle activities of PowerBANK are substantially equivalent to Safe Trace TX.

A6. Technological Characteristics

The technological characteristics of a transfusion management information system include the hardware and tool sets used to develop, test, implement, operate and maintain the product, along with the design methodology used during the life cycle of the product. The technological characteristics of PowerBANK, Safe Trace TX and SoftBank II are substantially equivalent.

B1. Non-clinical (System) Testing

The objective of the system test is to ensure the software system has met the intended use and meets all of the safety critical requirements. This is ensured through mapping the test procedures and test cases to the functional requirements and hazard analysis. The PowerBANK Enterprise Edition system testing was performed using test cases that were drafted according to defined test objectives to fulfill test requirements. Each test case is traceable to one or more test cases.

The approach to system testing was to use to use Manual Testing Process to test all the functional requirements and the Safety Critical Requirements with the use of manual test sheets and test cases prepared and executed for the same purpose. The summary of results of these test cases is included in section B3.

Prior to the completion of System Testing, all No Pass (fail) occurrences were resolved (either corrected or scheduled for future correction). All safety critical Issues were corrected. Re-execution of each corrected No Pass yielded Pass Situations for all occurrences.

In addition to System Test, other verification and validation efforts (unit testing, design reviews, GUI Validation Check, etc.) inherent in the development lifecycle have been performed on PowerBANK Enterprise Edition to help ensure the safety, quality, identity, potency and purity of blood and blood products and patient safety.

B2. Clinical (Beta) Testing

The purpose of the Beta test was to perform user validation and verification testing of PowerBANK Enterprise Edition in a user environment prior to the final release of the software.

West Parry Sound Health Centre, Parry Sound, Ontario, Canada was the location used to test PowerBANK Enterprise Edition. The Beta testing process promotes the identification of errors, inconsistencies and deviations in PowerBANK Enterprise Edition prior to final software release. As unexpected issues arose, they were addressed by MOSUM Technology (INDIA) Pvt. Ltd. through the use of Action Item Reports (AIR) a kind of Issue Tracking Spreadsheet and the Validation Documents.

A common Issue Tracking Spreadsheet was maintained for all the issues found while Beta testing of the product. Validation Documents existed for all the PowerBANK Enterprise Edition Software: Configuration, Enterprise Edition, and Interface.

The beta testing approach was similar to the system level approach and Manual Testing process was used. No automated testing was done during the process. Manual testing focused on testing the safety critical and non safety related. The results of the beta testing are included in B3.

Prior to completion of Beta Testing, all No Pass (fail) occurrences were corrected or scheduled for future correction. All issues related to the safety critical functionality were corrected. Re-execution of each corrected No Pass yielded Pass situations for all occurrences.

B3. Conclusions of Non-clinical and Clinical Testing
The System and Beta testing described above were two important steps in the overall verification and validation of PowerBANK Enterprise Edition, Version 1.0.

The following table summarizes manual test results at the System and Beta levels:

Summary of Manual Test Results for System and Beta Test			
	System Test	Beta Test	Total
Total Test Cases	1155	617	1772
Initial Test Case Failures	98	2	100
Test Case Failures on Re test	0	0	0