



**510(k) SUMMARY**  
Prepared 08/10/07

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

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**DEVICE NAME:**

Proprietary Name: IDM Symphony System, Version 2.0

Common Name: Blood Establishment Computer Software

Classification Name: To my knowledge FDA has not classified this device. The product code of 81MMH and Classification Name of Software, Blood-Bank, Stand Alone Products have been assigned to this device in the Classification Database.

**PREDICATE DEVICE:**

Information Data Management, Inc.:  
CDIS 1.0 (BK950037)  
Prelude 1.1 (BK050014)

**DEVICE DESCRIPTION:**

The IDM Symphony System is a suite of computer software that includes the Prelude (a donor management system) and Interlude (component/shipping module) applications, as well as other non-regulated modules. Each of the Symphony applications can operate stand-alone, or can be used together with third-party lab or donor management systems to become a complete blood collection and component manufacturing system. Symphony modules communicate with each other via off-the-shelf wired or wireless links, and interface with third party systems through standardized network connections. The system is intended to be "paperless", i.e. it supports self-administered health history



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and complete documentation of the physical exam and phlebotomy of blood donors, and aids in the manufacture of blood and blood products. Through the use of Symphony, one can perform required activities such as the tracking of donor deferral and demographic information, donation information including health history, test results, and tracking information for the manufacture and shipment of blood and blood components, i.e. recording of component processing information, from creation to shipment/disposal. Symphony supports the synchronization of data collected at mobile operations. The system is compatible with wired or wireless networks.

All Symphony applications use capabilities to control who can perform specific activities. A login mark (user ID) and password allows the system to uniquely identify each user as well as which activities each user may perform on the system.

The Symphony user's manual contains information that is common to all the modules within the Symphony suite of software. A separate user's manual for each individual application contains information that is specific to that particular module.

### **INTENDED USE:**

The IDM Symphony System is a computerized system intended to be used by trained personnel and blood donors to aid in and document the donation, manufacture and distribution of blood products. The system is intended to be "paperless", i.e. it supports self-administered health history and complete documentation of the determination of eligibility, physical exam and phlebotomy of blood donors, and aids in the manufacture, labeling and shipment of blood and blood products. Each of the Symphony applications can operate stand-alone, or can be used together with third-party lab or donor management systems to become a complete blood collection and component manufacturing system. Symphony modules communicate with each other via off-the-shelf wired or wireless links, and interface with third party systems through standardized network connections. The system is compatible with wired or wireless networks.



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**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS OF IDM SYMPHONY SYSTEM 2.0 TO PREDICATE DEVICES (IDM CDIS, 1.0 and IDM Prelude, 1.1)**

<b>CHARACTERISTIC</b>	<b>IDM SYMPHONY 2.0</b>	<b>IDM PRELUDE 1.1</b>	<b>IDM CDIS 1.0</b>
Application Language	Java	Java	C programming language & UNIX shell scripts
Database	Oracle RDBMS	Oracle RDBMS	Oracle RDBMS with SQL-Plus and SQL*Net
Server Operating System	XP or Windows 2000, Service Pack 2 or HP/UX 11.11	XP or Windows 2000, Service Pack 2	UNIX (SCO)
Client (Workstation) Operating System	MS Windows 2000, Service Pack 2 or XP	MS Windows 2000, Service Pack 2 or XP	N/A
Hardware Requirement - Client (Workstation)	INTEL Celeron processor (2.6 GHz) 1250mB Hard Disk, Ethernet compatible or wireless network, touch screen technology, Windows supported printers, Super VGA monitor w/1024x768 resolution	INTEL Celeron processor 1250mB Hard Disk, Ethernet compatible or wireless network, touch screen technology, Windows supported printers, Super VGA monitor w/1024x768 resolution	N/A
Hardware Requirement - Mobile Server	INTEL Pentium-IV processor, 18.25Gb Hard Disk, Ethernet compatible or wireless network supporting TCP/IP protocol, touch screen technology, Windows supported printers, Super VGA monitor w/1024x768 resolution	INTEL Pentium-IV processor, 18.25Gb Hard Disk, Ethernet compatible or wireless network supporting TCP/IP protocol, touch screen technology, Windows supported printers, Super VGA monitor w/1024x768 resolution	N/A
Hardware Requirement - Server	INTEL Pentium-IV processor, 42.25Gb Hard Disk, Ethernet compatible or wireless network supporting TCP/IP protocol, touch screen technology, Windows supported printers, Super VGA monitor w/1024x768 resolution	INTEL Pentium-IV processor, 42.25Gb Hard Disk, Ethernet compatible or wireless network supporting TCP/IP protocol, touch screen technology, Windows supported printers, Super VGA monitor w/1024x768 resolution	INTEL (or compatible) Pentium-class processor SCSI DAT drive (5GB) 3.5" (1.44MB) floppy drive SCO- and Ethernet-compatible network (if applicable) VGA monitor Digiboard supporting up to 8 peripheral devices
Memory (RAM) - Server	2Gb RAM	2Gb RAM	80 Mb
Memory (RAM) - Mobile server	2Gb RAM	2Gb RAM	N/A
Memory (RAM) - Client (Work-station)	256 Mb	256 Mb	N/A



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**SAFETY AND EFFECTIVENESS DATA:**

The IDM Symphony System, version 2.0 has been developed using an established procedure for software development, including non-clinical (unit, integration and system) and clinical (beta) testing. Unit testing was performed on each development log. Integration testing was performed as part of system testing. System testing was comprised of 24 test plans that confirmed that all modules performed as expected. Beta testing was performed at a blood center facility and was comprised of four test plans that primarily exercised the user-interface portions of the system.

In summary, the results of testing demonstrated that the IDM Symphony 2.0 system will be as safe, as effective, and will perform as well as the predicate devices when utilized within its intended use.