

510(k) SUMMARY

Prepared 0705/05

MANUFACTURER SUBMITTING 510(k) NOTIFICATION:

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DEVICE NAME:

Proprietary Name: IDM PRELUDE System, version 1.1
Common Name: Prelude
Classification Name: Software, Blood-Bank, Stand Alone Products

PREDICATE DEVICE:

Healthcare-ID, Donor – ID, Version 2.5 (BK030049)

DEVICE DESCRIPTION:

The IDM Prelude System is a stand-alone blood bank software device that supports self-administered health history and complete documentation of the physical exam and phlebotomy of blood donors. The system requires staff review of aberrant or missing donor responses. The User's Manual (Binder #2) supplied with this submission provides a complete description of the system's functionality.

INTENDED USE:

The IDM Prelude System is a computerized system intended to be used by blood donors and trained personnel to aid in and document the donation collection process, including donor demographics, health history, physical examination, eligibility determination and phlebotomy data. Prelude supports synchronization of data collected at mobile operations. The system interfaces with donor systems to allow for two-way communication of donor and donation information.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS OF IDM PRELUDE SYSTEM 1.1 TO PREDICATE DEVICE (Healthcare-ID, Donor – ID, Version 2.5)

<u>CHARACTERISTIC</u>	<u>IDM PRELUDE 1.1</u>	<u>Healthcare-ID, Donor – ID, Version 2.5</u>
Application Language	Java	Visual Basic
Database	Oracle RDMS	SQL Server
Server Operating System	XP or Windows 2000, Service Pack 2	MS Windows 2000
Client (Workstation) Operating System	MS Windows 2000, Service Pack 2 or XP	MS Windows 2000
Hardware Requirement – Client (Workstation)	INTEL Celeron processor, 2.6GHz, 1250mB Hard Disk, Ethernet compatible or wireless network card, touch screen monitor (Keytec, model J7PH-TA), Windows supported printers, Barcode scanner (Symbol model LS4004-1049), Digital camera (Logitech QuickCam Pro 4000), Signature Tablet, (Topaz Systems, SigTablet model T-L462-HSB)	Intel Pentium computer, touch screen technology, Windows supported printers
Hardware Requirement - Mobile Server	INTEL Pentium-IV processor, 18.25Gb Hard Disk, Ethernet compatible or wireless network card, touch screen technology, Windows supported printers	Intel Pentium computer, touch screen technology, Windows supported printers
Hardware Requirement - Client (Workstation) Server	INTEL Pentium processor, 42.25Gb Hard Disk, Ethernet compatible or wireless network card, touch screen technology, Windows supported printers	Intel Pentium computer, touch screen technology, Windows supported printers
Memory (RAM) – Client (Work-station) Server	2Gb RAM	Not known
Memory (RAM) – Mobile server	2Gb RAM	Not known
Memory (RAM) – Client (Work-station)	256 Mb	Not known

SAFETY AND EFFECTIVENESS DATA:

The IDM Prelude System, version 1.1 has been developed using an established procedure for software development. This system will be as safe, as effective, and will perform as well as the predicate device when utilized within its intended use, as demonstrated by the clinical and non-clinical testing performed.

Non-Clinical Testing: The assessment of the results of non-clinical (unit/integration and system) testing can be found in Binder #1, Tab #6, Unit Testing, and Tab #7, Integration/System (Alpha) Testing.

Clinical Testing: The assessment of the results of clinical (beta) testing can be found in Binder #1, Tab #8, Beta Testing Activity.