

**510(k) SUMMARY**  
Prepared July 31, 2001

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

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**DEVICE NAME:**

Proprietary Name: IDM SURROUND System, version 3.0  
Common Name: Surround  
Classification Name: Software, Blood-Bank, Stand Alone Products

**PREDICATE DEVICE:**

IDM SURROUND System, versions 1.0 and 2.0

**DEVICE DESCRIPTION:**

The IDM Surround System is a stand-alone blood bank software device that aids in the interpretation and management of laboratory test results. The software assists laboratories by collecting and collating sample IDs and their test results, and transferring the results automatically to configurable, sample specific locations. A variety of reporting options are available, e.g. facsimile, electronic mail, File Transfer Protocol (FTP), serial transfer (direct cable), print/mail, etc.

Surround is a secure system requiring a login mark (user ID) and password for system access. Individual capabilities are maintained for each user to control the performance of specific system activities. This information allows Surround to uniquely identify each user as well as which activities multi-level users may perform on the system. In general, users with appropriate capabilities can find, create and inquire about all testing records. The User's Manual (Binder #2) supplied with this submission provides a complete description of the software.

**INTENDED USE:**

The IDM Surround System is a computerized system intended to be used by trained personnel as an aid in the collection, collation and management of data generated by the laboratory testing of donor or patient blood samples.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS OF IDM SURROUND SYSTEM, VERSION 3.0 TO IDM SURROUND SYSTEM, VERSION 2.0:**

<u>CHARACTERISTIC</u>	<u>IDM SURROUND 3.0</u>	<u>IDM SURROUND 1.0/2.0 (Predicate Device)</u>
Application Code	Java	Java
Compiler	Java Runtime Executable (JRE)	Java Runtime Executable (JRE)
Application Operating System	Microsoft Windows NT	Microsoft Windows NT
Database	Oracle RDBMS	Oracle RDBMS
Minimum Hardware Requirement	INTEL 300 MHz Pentium, 4GB Hard Disk with CD ROM, Super VGA color monitor and video board, Network Interface card, mouse, keyboard, Serial communications port	INTEL 300 MHz Pentium, 4GB Hard Disk with CD ROM, Super VGA color monitor and video board, Network Interface card, mouse, keyboard, Serial communications port
Serial Connector	PC Serial Port	PC Serial Port
Minimum Memory (RAM)	128 MB RAM	128 MB RAM

**SAFETY AND EFFECTIVENESS DATA:**

The IDM Surround System, version 3.0 has been developed using an established procedure for software development. This system will be as safe, as effective, and will perform as well as or better than 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, Tabs #6, #7 and #8.

Clinical Testing: The assessment of the results of clinical (beta) testing can be found in Binder #1, Tab #9.