## MANUFACTURER SUBMITTING 510(K) NOTIFICATION:

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## DEVICE NAME:

Proprietary Name:      LifeTrak®/Donor, Version 3.01
Common Name:        Software, Blood Bank, Stand Alone
Classification Name:    Unclassified

## PREDICATE DEVICES:

LifeTrak®/Donor, version 2.03 - BK990027
IDM Prelude, version 1.1.0 –BK050014

## DEVICE DESCRIPTION:

The LifeTrak®/Donor System is a stand-alone blood bank software device that aids in the management of blood donors, their eligibility status, donations, deferrals, notification, communication, registration with health history and physical findings, an on-line donor questionnaire to be utilized by center staff and/or the donor, special donation registration, and HLA/RBC capabilities. Additionally, LifeTrak®/Donor includes mobile recruitment, telerecruitment, fixed site management, staff scheduling, and production control/transportation.

## INTENDED USE:

LifeTrak/Donor is a computerized system intended to be used by trained staff who are actively engaged in functions that encompass:

- Maintaining a reliable donor database
- Rolling donor eligibility status
- Registering and auditing donations and deferrals

- On-line health history, physical findings, and donor questionnaire
- Inter-active donor questionnaire (staff and/or donor)
- Maintaining accurate records of communication with donors
- Donor notification
- HLA/RBC searching and matching
- Special donations registration
- Organizing mobile recruitment and telerecruitment activities
- Planning, scheduling, and conducting drives
- Donor scheduling
- Scheduling collection staff
- Maintaining collection goals and calculating achievement statistics
- Production control and transportation for collection activities

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE DEVICE:**

| Characteristic | LifeTrak/Donor, 3.01 | LifeTrak/Donor, 2.03 BK990027 | Prelude, 1.1 BK050014 |
|---|---|---|---|
| Database | Oracle RDMS | Oracle RDMS | Oracle RDMS |
| Programming Language | Oracle Forms and Reports SQL | Oracle Forms and Reports SQL | Java |
| Server Operating System | Unix based operating systems: HP-UX 11.00 Linux AS 2.1 Linux ES 2.1 | Unix based operating systems: HP-UX 11.00 Linux AS 2.1 Linux ES 2.1 Linux 7 | Windows XP Windows 2000, SP 2 |
| Server Hardware | HP 9000 PA-RISC based processor 1 GB RAM or more 18 GB system d36 GB data disk or more 4mm DAT Intel CISC based processor 1GB RAM or more 36 GB available disk or more 4mm DAT | HP 9000 PA-RISC based processor 1 GB RAM or more 18 GB system d36 GB data disk or more 4mm DAT Intel CISC based processor 1GB RAM or more 36 GB available disk or more 4mm DAT | INTEL Pentium processor 42.25 GB hard disk Ethernet compatible or wireless network card Touch screen technology Windows supported printers |
| Client Operating System (workstation) | MS Windows 2000 or XP | MS Windows 2000 or 98 | MS Windows 200, Service Pack 2 or XP |
| Client Hardware (workstation) | Pentium processor 400 MHz+ 128 MB RAM base memory 800 MB disk available | Pentium processor 266 MHz+ 128 MB RAM base memory 800 MB disk available | Intel Celeron processor, 2.6 GHz 1250 MB Hard Disk Ethernet compatible or wireless network card |