

510(K) SUMMARIES

In accordance with 21 CFR 807.92, Mediware submits the following 510(k) Summary for LifeTrak® 2018, blood bank stand-alone software device:

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MANUFACTURER SUBMITTING 510(K) NOTIFICATIONS:

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DEVICE NAME:

Proprietary Name: LifeTrak® 2018
Common Name: Software, Blood Bank, Stand Alone
Classification Name: Class II

PREDICATE DEVICE:

LifeTrak® 2018

DEVICE DESCRIPTION:

LifeTrak® 2018 is a Blood Establishment Computer Software stand-alone device that consists of three separate subsystems performing in a single database. LifeTrak is modular by design so that the functionality of one module may have no impact on other modules or functions within the system. This flexibility allows the system to serve as a multifunctional application for all areas of a donor center and high-volume testing services. Safety critical functions related to reliable donor management, component manufacturing, labeling, testing, and other functions as indicated. LifeTrak is designed for high-availability and is capable of processing, storing and retrieving donor center data for large operations. Since first marketing of the product, users of the system, users have

experienced exceptional performance and reliability. LifeTrak® is usable with wired/wireless networks supporting TCP/IP protocol. Listed below are the three sub-systems:

Donor is 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), web-based health history questionnaire, Maintaining accurate records of communication with donors, Donor notification, HLA/RBC searching and matching, Special donations registration, Organizing mobile recruitment and tele recruitment 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.

Laboratory (Lab) is intended to be used by trained personnel as a tool in the management of data related component production, testing, and labeling of donated blood and testing of external samples. User access to individual modules is controlled through defined access levels. Modules may be used independently and include the import blood processing, and high-volume testing services (Regional Sample Management).

Product Management (Distribution) is intended to be used by trained personnel as a tool in the management of data related to order processing, inventory management, distribution (packing and shipping), transfers, and customer debit/credit. User access to individual modules is controlled through defined access levels. Modules may be used independently and include the following: Order Module, Distribution Module, Inventory Management, Offline Data Entry, Customer Credit/Debit.

INDICATION FOR USE:

LifeTrak is a comprehensive, modular, computerized system intended to be used by trained personnel as a tool in the management of data processes performed by staff at blood centers and high-volume testing services. User access to individual modules is controlled through defined access levels. Individual staff may be actively engaged in functions that encompass the following:

- Dynamic donor eligibility status
- Register, track, and audit donations and deferrals
- On-line health history, physical findings, and collection process
- Inter-active donor questionnaire (staff and/or donor/remote donor)
- HLA/RBC search and match
- Donor schedules

- Component production and modification
- Testing
- Labeling
- Imported Blood Processing
- Inventory Management
- Distribution
- Material Check-In
- Offline Data Entry (Re-entry if downtime)
- LifeTrak is usable with wired/wireless networks supporting TCP/IP protocols

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE DEVICES:

The following tables provide a detailed comparison of the technological characteristics of LifeTrak® 2012 to the predicated devices:

Characteristic:	LifeTrak® 2012	LifeTrak® 2018
Database	Oracle Standard Edition (SE) Oracle 11g (11.2.0.3) for Linux Intel. Oracle Fusion Middleware (FMW) 11g (11.1.2) Oracle Forms and Reports for Linux Intel. Oracle Web Logic Server 10.3.5 Oracle JDK 1.6.0_29	Oracle RDBMS(Database) Server 12.2.0.1– 64 Bit Weblogic Server 12.2.1.0 - 64 Bit Fusion middleware (Forms and reports) (12.2.1.0) – 64 Bit Oracle JDK 1.8.0_151

Characteristic:	LifeTrak® 2012	LifeTrak® 2018
Server Operating System	VMWARE ESXI 4.1 Oracle Linux Release 5 Update 7 (64-bit) Or Red Hat Enterprise Linux ES Release 5 Update 7 (64-bit)	Oracle Linux 7.2 x86-64(. i.e. 64 bit)
Server Hardware	1x Intel® Xeon® E5504 (4 core, 2.00 GHz, 4MB L3, 80W) 12 GB Memory Integrated RAID controller 2 x 72 GB disks in RAID1 configuration (72 GB useable) 2 x 146GB disks in RAID1 configuration (146 GB useable) 2 x PCI Gigabit Ethernet Base T LAN adapter	<ul style="list-style-type: none"> • 1 x Intel® Xeon® E5504 (4 core, 2.00 GHz, 4MB L3, 80W) • 8 GB memory (VM configuration) • Integrated RAID controller • 2 x 72 GB disks in RAID1 configuration (72 GB useable) • 2x146GB disks in RAID1 configuration • 2 x PCI Gigabit Ethernet BaseT LAN adapter • 1 x 20/40 GB DDS-4 4mm internal DAT tape drive • Redundant power supply • Redundant fan kit

Characteristic:	LifeTrak® 2012	LifeTrak® 2018
Client Operating System – Workstation	Microsoft Windows 7 OR Microsoft Windows XP SP2/SP3 Internet Explorer Version 7, 8, or 9 Java JRE Version 1.6.0_29 Adobe Acrobat Reader Version 9 or 10	2.26 GHz CPU 4 GB RAM 80 GB Hard Drive Intel 10/100 Ethernet Network Interface Microsoft Windows 7 Or Microsoft Windows 7 Internet Explorer Version 11 JAVA JRE Version 1.8.0_161 Adobe Acrobat Reader Version Standard DC
Client Hardware - Workstation	2.26 GHz CPU 4 GB RAM 80 GB Hard Drive Intel 10/100 Ethernet Network Interface Printers: HP LaserJet 4000 HP LaserJet 4015 HP LaserJet 4050 Bar Code Scanners: Symbol DS6708-SR20007ZZR Symbol LS2208-SR20401R Symbol LS2208-SR20371R Symbol LS 4208	2.26 GHz CPU 4 GB RAM 80 GB Hard Drive Intel 10/100 Ethernet Network Interface Printers: HP LaserJet 4000 HP LaserJet 4015 HP LaserJet 4050 Bar Code Scanners: Symbol DS6708-SR20007ZZR Symbol LS2208-SR20401R Symbol LS 2208-SR20371R (No Codabar concatenation.) Symbol LS 4208 Zebra DS8108

Characteristic:	LifeTrak® 2012	LifeTrak® 2018
Mobile PC Operating System	Microsoft Windows Server 2008 R2	Microsoft Windows Server 2012 R2
Mobile PC Hardware	2.26 GHz CPU 4 GB RAM 250 GB Hard Disk 10/100/1000 Ethernet NIC Intel 5100 Wireless Network Card Battery	2.26 GHz CPU 4 GB RAM 250GB hard disk 10/100/1000 Ethernet NIC Intel 5100 wireless network card Battery
Database	Oracle Standard Edition (SE) Oracle 11g (11.2.0.3) for Linux Intel Oracle Fusion Middleware (FMW) 11g (11.1.2) Oracle Forms and Reports for Linux Intel Oracle Web Logic Server 10.3.5 Oracle JDK 1.6.0_29	Oracle Database 12c (12.2.0.1) standard edition Oracle Fusion Middleware (FMW) 12c (12.2.1.0) Forms and Reports for MS Windows Oracle Web Logic Server 12.2.1.0 Oracle JDK 1.8.0_161 Internet Explorer Version 11 JAVA JRE Version 1.8.0_121 Adobe Acrobat Reader Version Standard DC
Server Operating System	VMWARE ESXi 4.1 Oracle Linux Release 5 Update 7 (64 Bit) OR Red Hat Enterprise Linux ES Release 5 Update 7 (64-bit)	Win 2012 R2 standard for 64 bit

Characteristic:	LifeTrak® 2012	LifeTrak® 2018
Database Server Hardware	<p>1 x Intel® Xeon®E5504 (4 core, 2.00 GHz, 4MB L3, 80W)</p> <p>12 GB Memory</p> <p>Integrated RAID Controller</p> <p>2 x 72 GB disks in RAID1 configuration (72 GB useable)</p> <p>2 x 146GB disks in RAID 1 configuration</p> <p>2 x PCI Gigabit Ethernet BaseT LAN adapter</p>	<p>1 x Intel® Xeon® E 7-2803 (1.73 GHz dual core)</p> <p>8 GB RAM</p> <p>250GB hard disk</p>
Client Hardware – Workstation	<p>2.26 GHz CPU</p> <p>4 GB RAM</p> <p>80 GB Hard Drive</p> <p>Intel 10/100 Ethernet Network Interface</p> <p>Printers: HP Laser Jet 4000 HP Laser Jet 4015 HP Laser Jet 4050</p> <p>Bar Code Scanners: Symbol DS 6708-SR20007ZZR Symbol LS 2208-SR20401R Symbol LS 4208</p>	<p>2.26 GHz CPU</p> <p>4 GB RAM</p> <p>80 GB Hard Drive</p> <p>Intel 10/100 Ethernet Network Interface</p> <p>Printers: HP Laser Jet 4000 HP Laser Jet 4015 HP Laser Jet 4050</p> <p>Bar Code Scanners: Symbol DS 6708-SR20007ZZR Symbol LS 2208-SR20401R Symbol LS 4208 Zebra DS8108</p>

Characteristic:	LifeTrak® 2012	LifeTrak® 2018
Client Software – Workstation	Microsoft Windows 7 OR Microsoft Windows XP SP2/SP3 Internet Explorer Version 7,8, or 9 JAVA JRE Version 1.6.0_29 Adobe Acrobat Reader Version 9 or 10 WinWedge 3.4.2 (Serial software interface for scale. LifeTrak Lab only.)	Microsoft Windows 7 OR Microsoft Windows 10 Internet Explorer Version 11 JAVA JRE Version 1.8.0_151 Adobe Acrobat Reader Version 11
Hematrax Print Server PC Workstation Hardware	2.4 GHz CPU CD ROM 2 GB RAM 80 GB Internal Disk Ethernet 10/100 NIC Serial port for each serially connected printer	PC Workstation for Hematrax Print Server 2.4 GHz Celeron Processor CD ROM 1 GB RAM 40 GB internal disk Ethernet 10/100 NIC Serial port for each serially connected printer
Hematrax Integration Server Software	VMWARE ESXi 5 (optional) Microsoft Windows Server 2008 R2 Digi-Trax Hematrax 3.0.3	VMware ESXi 5.x Hematrax Unity Print Server v8.0 Leave Windows Server 2008 R2

Characteristic:	LifeTrak® 2012	LifeTrak® 2018
Barcode Printers	Digi-Trax Zebra BB-ZM400+ Digi-Trax Zebra Z-4M BBE+ Digi-Trax Zebra 4000BB With Digi-Trax printer firmware and 300 dots per inch (dpi) print head for ISBT compatibility.	Digi-Trax Zebra ZT-410 Digi-Trax Zebra 4000BB Digi-Trax Zebra Z-4M BBE+ Digi-Trax Zebra BB-ZM400+
Scales	Sartorius TE6100 Sartorius BL6 Sartorius PT6 AND EK6000G Mettler Toledo Viper PM BM 6	Sartorius TE6100 Sartorius BL6 Sartorius PT6 AND EK6000G Mettler Toledo Viper PM BM 6
Camera	NA	Microsoft - VX-5000
Signature Pad	NA	Topaz Systems – T-L460-HSB-R

LifeTrak® 2018 was developed using an established design control process for software development. The product was subjected to extensive verification and validation testing including system testing to ensure the product meets its intended use including safety critical requirements. Nonclinical (alpha) testing was performed by Mediware and demonstrates that LifeTrak® 2018 meets the requirements for intended use.

Clinical/user site (use acceptance) testing was conducted to validate LifeTrak® 2018. The results of user sites testing demonstrated that LifeTrak® 2018 meets the required specifications and functioned as expected with no degradation in response times.

Conclusions:

Mediware Information Systems, Inc. concludes that LifeTrak® 2018 is substantially equivalent to the predicate devices listed in that it has the same intended use with similar technological features and capabilities. LifeTrak® 2018 provides some minor extensions of the functional capabilities. Testing was conducted as required by Mediware’s Design Control Validation and Verification processes to evaluate these changes in functional capabilities of LifeTrak® 2018. The results of this testing demonstrate that LifeTrak® 2018 performs as expected and that the minor changes in functional capabilities do not affect safety or effectiveness.