510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

K130794

B. Purpose for Submission:

The CELL TRACKS ANALYZER II® System Software is being modified from the current version (2.5.1) to Version 2.6.0 and a Remote Review Workstation is available that supports connections to the customer Local Area Network (LAN) to provide the following network-based features: Remote Review of Results, Archive Results and Export reports to Network File Share, and Transfer Results to the Laboratory Information System (LIS). The application software was modified and new software modules were created to implement the networking capability.

C. Manufacturer and Instrument Name:

Veridex, LLC

CELLTRACKS ANALYZER II® System

D. Type of Test or Tests Performed:

In vitro diagnostic device to aid in the enumeration of immunomagnetically selected and fluorescently identified circulating tumor cells of epithelial origin in whole blood for prediction of cancer progression and survival.

E. System Descriptions:

1. Device Description:

The CELLTRACKS ANALYZER II® is a semi-automated fluorescence microscope, consisting of the analyzer, a dedicated computer with CELLTRACKS® software, monitor, keyboard, mouse and uninterruptible power supply (UPS). The system also supports an optional Remote Review Workstation, which consists of a dedicated computer with CELLTRACKS® software, monitor, keyboard and mouse. Use of this product requires training and should be used under the supervision of laboratory management.

The CELLTRACKS ANALYZER II® is for analysis of rare cells that are isolated from biological fluids including whole blood. It is used in conjunction with the CELLTRACKS® AUTOPREP® System, which automates and standardizes the sample preparation with specific reagent kits. The optional Remote Review Workstation

provides the capability to review images and report results remotely.

2. Principles of Operation:

   The CELLTRACKS ANALYZER II® is used in conjunction with the CELLTRACKS® AUTOPREP® System and reagent kits that contain ferrofluid-based capture reagent and immunofluorescent reagents for detection and characterization of the captured cells. The ferrofluid reagent consists of particles with a magnetic core surrounded by a polymeric layer coated with antibodies that target the cells of interest. After immunomagnetic capture and enrichment, fluorescent reagents are added for identification and enumeration of the target cells.

   The processed reagent/sample mixture is dispensed by the CELLTRACKS® AUTOPREP® System into a cartridge that is inserted into a MAGNEST® Cartridge Holder. The strong magnetic field of the MAGNEST® Cartridge Holder causes the magnetically-labeled target cells to move to the surface of the cartridge. The CELLTRACKS ANALYZER II® scans the entire surface of the cartridge with a series of fluorescence filters that are defined for a given assay. Cell images from each filter are presented in a gallery format for final cell classification by the operator.

3. Modes of Operation:

   Semi-automated, one-at-a-time analysis.

4. Specimen Identification:

   The CELLTRACKS® AUTOPREP® System records the associated sample, patient, reagent, and test information to the MAGNEST® Data Button, which is an EEPROM storage device embedded on the bottom of the MAGNEST® Cartridge Holder. The Data Button is then read on the CELLTRACKS ANALYZER II® when the MAGNEST® Cartridge is loaded and the information is transferred to the CELLTRACKS ANALYZER II® database. This information tracks with the sample and is included in any subsequent reports.

5. Specimen Sampling and Handling:

   The processed reagent/sample mixture is dispensed by the CELLTRACKS® AUTOPREP® System into a sample cartridge that is inserted into a MAGNEST® Cartridge Holder. The MAGNEST® Cartridge Holder is loaded onto the sample stage of the CELLTRACKS ANALYZER II® manually and then the surface of the sample cartridge is automatically scanned. The users then manually review the images and interpret the results. When the scan is complete, the system ejects the stage, and unlocks the door. The operator removes the MAGNEST® Cartridge Holder.

6. Calibration:

   The analyzer is calibrated using the CELLTRACKS® System Verification Cartridge which contains a strip of fluorescent material. System verification checks the optical performance and chamber "skew" which ensures proper scanning. There is no recognized reference material or method.

7. Quality Control:

   For the circulating tumor cell assay the CELLSEARCH® Circulating Tumor Cell Control Kit should be used following the Instructions for Use of the CELLSEARCH® Circulating Tumor Cell Control Kit.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes ____X____ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR 866.6020, Immunomagnetic circulating cancer cell selection and enumeration system.

2. Classification:

   II

3 Product code:

   NQI, System, immunomagnetic, circulating cancer cell, enumeration

4. Panel:

   Pathology (88)

G. Intended Use:

1. Indication(s) for Use:

   The CELLTRACKS ANALYZER II® is a semi-automated fluorescence microscope used to enumerate fluorescently labeled cells that are immunomagnetically selected and aligned. This product is for in vitro diagnostic use when used in tandem with specimen

preparation equipment and reagents that are legally marketed for in vitro diagnostic use with this device.

2. Special Conditions for Use Statement(s):

   For prescription use only

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   CELLTRACKS ANALYZER II® System, k113181

2. Comparison with Predicate Device:

Similarities		
Item	Modified CELLTRACKS ANALYZER II® v2.6.0	Current CELLTRACKS ANALYZER II® v2.5.1 (k113181)
Indications for Use	The CELLTRACKS ANALYZER II® is a semi-automated fluorescence microscope used to enumerate fluorescently labeled cells that are immunomagnetically selected and aligned. This product is for in vitro diagnostic use when used in tandem with specimen preparation equipment and reagents that are legally marketed for in vitro diagnostic use with this device.	Same
Operating System	Debian Linux 5	Same
Image Acquisition Algorithms	-	Same
Analysis Algorithms	-	Same
Cell Selection Algorithms	-	Same
Sample	Processed via Magnest	Same
Available Channels for Analysis	4	Same

Differences		
Item	Device	Predicate
Software Version	Software version 2.6.0	Software version 2.5.1
Remote Review Workstation PC	Included	Not included
Networking: • Remote Review of Results • Archive Results to a Network File Share • Export Report or Images to Network File Share • Transfer Results to LIS Interface	Included	Not included
System Data Backup and Recovery	Manual (all database tables), option for an Automatic Backup (includes database tables plus in-process results)	Manual (all database tables)

I. Special Control/Guidance Document Referenced (if applicable):

Not applicable

J. Performance Characteristics*:*

1. Analytical Performance:

a. Accuracy:

Not applicable

b. Precision/Reproducibility:

Not applicable

c. Linearity:

Not applicable

d. Carryover:

Not applicable

e. Interfering Substances:

Not applicable

2. Other Supportive Instrument Performance Data Not Covered Above:

Different levels of software testing, including Development Testing, Verification Testing and Validation Testing, were performed to verify and validate the software changes. Testing documentation was provided for the Verification Testing and the Validation Testing.

The Verification Testing included Software Function Testing, DTR (Development Track Record) Testing, Regression Testing, Stress Testing and Mater Disk Testing. The Software Function Testing was performed on the CellTracks Analyzer II and the Remote Review Station, as well as the interaction of the two with each other, to verify that adequate software functions were implemented. The DTR Testing was performed to test the effectiveness of corrections implemented for software anomalies uncovered during the development and testing process. The purpose of the Stress Testing was to create series of test cases that vary normal interactions of the CellTracks Analyzer II, Remote Review Station, Laboratory Information System and Networking to cause stress on the software application. The resulting set of tests showed that the interaction of various software features does not cause unexpected performance issues. The Master Disk Testing was performed on the final software to verify that the software installed properly on both the CellTracks Analyzer II and the Remote Review Station. All verification activities were considered as executed and passed for both the CellTracks Analyzer II and the Remote Review Station.

The Validation Testing was performed by mimicking user-like operation of the instrument. System Verification Cartridge (SVC), Fluorescent Magnetic Beads and Control samples were scanned with the predicate software (v2.5.1) and with the new device software (v2.6.0) over the course of 4 days to confirm that performance is equivalent across software versions. One CELLTRACKS Analyzer II along with a Remote Review Station was used for this testing. The following operations were performed and results were compared between software versions.

- SVC cartridges were scanned 6 times with the old and new software to demonstrate that the six scan locations on the cartridge passed the instrument check values (a pass/fail result). Additional SVC scans were performed across days since it is a daily instrument check that must pass prior to sample or control scanning.
- Sample cartridges were filled with fluorescent magnetic beads and scanned as patient samples. One bead control was scanned 16 times (across 2 days) with each version of software. The counts were compared across software versions.
- Sixteen control cells processed on the CELLTRACKS® AUTOPREP® System were scanned across the two versions of software (across 2 days). Eight samples were scanned first with v2.5.1 and re-scanned on v2.6.0. Another set of eight were scanned first with v2.6.0 and re-scanned with v2.5.1. The high and low control counts were compared across software versions.
- Gallery review printouts of control cells and beads for a total of 4 controls samples (8 printouts) and 4 bead samples (8 printouts) from the CellTracks Analyzer II and the RRW matched identically showing that the images displayed are the same on both instruments.

- All control and bead sample results were archived per CellTracks Analyzer II User Guide for the v2.6.0 and per CellTracks Analyzer II User Guide for the v2.5.1. The System log files and SVC log files were exported from the v2.6.0 hard drive and from the v2.5.1 hard drive. The System Log Files were inspected for Error Codes.

All system validation test results met the acceptance criteria. No error codes were posted during the testing.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.