Summary Information

AUG 2 6 2010

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K100684

1. Submitter name, address, contact	Veridex, LLC 1001 U.S. Route 202 Raritan, NJ 08869 Contact Person: Sarah McManus
2. Preparation Date	Date 510(k) prepared: March 9, 2010
3. Device name	Trade or Proprietary Name: CellTracks® AutoPrep® System Common Name: Blood cell diluting equipment Classification Name: Automated Blood Cell Diluting Apparatus (21 CFR 864.5240, Product Code GKH)
4. Predicate device	The predicate device is the CellTracks® AutoPrep® System (K040077, March 12, 2004)

5. Device Description

The CellTracks® AutoPrep® System is a general purpose laboratory instrument used with immunomagnetic reagents that capture and enrich target cells, and labeling reagents that differentiate cells in whole blood. The CellTracks® AutoPrep® System processes up to 8 samples in a batch, performing all required process steps, including red cell detection, plasma aspiration and final transfer to the analysis cartridge. The user is prompted to perform various pre-processing operations such as dilution and centrifugation. Cell analyzers such as the CellTracks Analyzer II®, CellSpotter® System, flow cytometers or microscopes may be used for cell identification and enumeration following processing.

The AutoPrep® system uses a series of immunomagnetic separation procedures to isolate the cells of interest and to stain the cells with fluorescence-labeled monoclonal antibodies.

6. Device intended use

The CellTracks® AutoPrep® System is a general purpose laboratory instrument used with immunomagnetic reagents that capture and enrich target cells, and labeling reagents that differentiate cells in whole blood. Cell analyzers such as the CellTracks Analyzer II®, CellSpotter® System, flow cytometers or microscopes may be used for cell identification and enumeration. The system is for in vitro diagnostic use.

7. Comparison to predicate device

The CellTracks® AutoPrep® System (modified) is substantially equivalent to the CellTracks® AutoPrep® System (current - K040077: March 12, 2004). There has been no change to intended use, fundamental scientific technology, mode of operations, or specimen type/identification.

Changes from the predicate include:

1) New make and model of waste bottle accessory.
2) Labeling changes associated with the accessory waste bottle and the waste bottle handling procedure.

8. Conclusions

The information presented in the premarket notification demonstrates that the performance of the CellTracks® AutoPrep® System (modified) is substantially equivalent to the predicate device.

Equivalence was demonstrated through functional testing of the bulk fluid module as well as performance testing using quality control samples.

The information presented in the premarket notification provides a reasonable assurance that the CellTracks® AutoPrep® System (modified) is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Veridex, LLC
c/o Ms. Sarah McManus
Manager, Regulatory Affairs
1001 US Highway 202 North
Raritan, New Jersey 08869

AUG 26 2010

Re: k100684
Trade/Device Name: CellTracks® AutoPrep® System
Regulation Number: 21 CFR 864.5240
Regulation Name: Automated blood cell diluting apparatus
Regulatory Class: Class I
Product Code: GKH
Dated: July 23, 2010
Received: July 26, 2010

Dear Ms. McManus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D.
Director,
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Device and Radiological Health

Enclosure

K100684

Indication for Use

AUG 26 2010

510(k) Number (if known): K100684

Device Name: CellTracks® AutoPrep® System

Indication For Use:
The CellTracks® AutoPrep® System is a general purpose laboratory instrument used with immunomagnetic reagents that capture and enrich target cells, and labeling reagents that differentiate cells in whole blood. Cell analyzers such as the CellTracks Analyzer II®, CellSpotter® System, flow cytometers or microscopes may be used for cell identification and enumeration. The system is for in vitro diagnostic use.

Prescription Use __X___ And/Or Over the Counter Use ___.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K100684