DEC 2 1 2010

Summary Information

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: k103502

1.	**Submitter name, address, contact**	Veridex, LLC 1001 U.S. Route 202 Raritan, NJ 08869 Contact Person: Sarah McManus
2.	**Preparation Date**	Date Special 510(k) prepared: 23 November 2010
3.	**Device name**	Trade or Proprietary Name: CellSearch® Circulating Tumor Cell Kit Common Name: CellSearch® Circulating Tumor Cell Kit Classification Name: Immunomagnetic circulating cancer cell selection and enumeration system (21 CFR 866.6020, Product Code NQI)
4.	**Predicate device**	The predicate device is the CellSearch® Circulating Tumor Cell Kit (K073338, February 26, 2008)

5. Device Description

The CellSearch® Circulating Tumor Cell Kit contains a ferrofluid-based capture reagent and immunofluorescent reagents. The ferrofluid reagent consists of small particles with a magnetic core surrounded by a polymeric layer coated with antibodies targeting the EpCAM antigen for capturing CTC. After immunomagnetic capture and enrichment, fluorescent reagents are added for identification and enumeration of CTC. The fluorescent reagents include the following: anti-CK-Phycoerythrin (PE) specific for the intracellular protein cytokeratin (characteristic of epithelial cells), DAPI, which stains the cell nucleus, and anti-CD45-Allophycocyanin (APC) specific for leukocytes.

The reagent/sample mixture is dispensed by the CellTracks® AutoPrep® System into a cartridge that is inserted into a MagNest® cell presentation device. The strong magnetic field of the MagNest® device attracts the magnetically labeled epithelial cells to the surface of the cartridge. The CellTracks Analyzer II® or CellSpotter® Analyzer automatically scans the entire surface of the cartridge, acquires images and displays any event to the user where CK-PE and DAPI fluorescence are co-located. Images are presented to the user in a gallery format for final classification. An event is classified as a tumor cell when its morphological features are consistent with that of a tumor cell and it exhibits the phenotype EpCAM+, CK+, DAPI+ and CD45-.

6. Device intended use

The CellSearch® Circulating Tumor Cell Kit is intended for the enumeration of circulating tumor cells (CTC) of epithelial origin (CD45-, EpCAM+, and cytokeratins 8, 18+, and/or 19+) in whole blood. The presence of CTC in the peripheral blood, as detected by the CellSearch® Circulating Tumor Cell Kit, is associated with decreased progression free survival and decreased overall survival in patients treated for metastatic breast, colorectal or prostate* cancer. The test is to be used as an aid in the monitoring of patients with metastatic breast, colorectal or prostate cancer. Serial testing for CTC should be used in conjunction with other clinical methods for monitoring metastatic breast, colorectal and prostate cancer. Evaluation of CTC at any time during the course of disease allows assessment of patient prognosis and is predictive of progression free survival and overall survival.

**Metastatic prostate cancer patients in this study were defined as having two consecutive increases in the serum marker PSA above a reference level, despite standard hormonal management. These patients are commonly described as having androgen-independent, hormone-resistant, or castration-resistant prostate cancer.*

7. Comparison to predicate device

The CellSearch® Circulating Tumor Cell Kit (modified) is substantially equivalent to the CellSearch® Circulating Tumor Cell Kit (current - K073338: February 26, 2008). There has been no change to intended use, fundamental scientific technology, mode of operations, or specimen type/identification.

Changes from the predicate consist of labeling changes to assist the operator in identifying the presence and correct sequence of each reagent in the reagent tray.

8. Conclusions

The information presented in the premarket notification demonstrates that the performance of the CellSearch® Circulating Tumor Cell Kit (modified) is substantially equivalent to the predicate device.

Equivalence was demonstrated through verification of the labeling specifications for the modified device and labeling process validation.

The information presented in the premarket notification provides a reasonable assurance that the CellSearch® Circulating Tumor Cell Kit (modified) is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Veridex, LLC
c/o Ms. Sarah McManus
Manager, Regulatory Affairs
1001 US Hwy 202 North
Raritan, NJ 08869

DEC 2 1 2010

Re: k103502
Trade/Device Name: CellSearch™ Circulating Tumor cell Kit
Regulation Number: 21CFR§866.6020
Regulation Name: Immunomagnetic Circulating Cancer Cell Selection and Enumeration system
Regulatory Class: Class II
Product Code: NQI
Dated: November 23, 2010
Received: November 29, 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

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

Enclosure

Indications for Use

510(k) Number (if known): k103502

DEC 21 2010

Device Name: CellSearch® Circulating Tumor Cell Kit

Indication For Use:
The CellSearch® Circulating Tumor Cell Kit is intended for the enumeration of circulating tumor cells (CTC) of epithelial origin (CD45-, EpCAM+, and cytokeratins 8, 18+, and/or 19+) in whole blood. The presence of CTC in the peripheral blood, as detected by the CellSearch® Circulating Tumor Cell Kit, is associated with decreased progression free survival and decreased overall survival in patients treated for metastatic breast, colorectal or prostate* cancer. The test is to be used as an aid in the monitoring of patients with metastatic breast, colorectal or prostate cancer. Serial testing for CTC should be used in conjunction with other clinical methods for monitoring metastatic breast, colorectal and prostate cancer. Evaluation of CTC at any time during the course of disease allows assessment of patient prognosis and is predictive of progression free survival and overall survival.
**Metastatic prostate cancer patients in this study were defined as having two consecutive increases in the serum marker PSA above a reference level, despite standard hormonal management. These patients are commonly described as having androgen-independent, hormone-resistant, or castration-resistant prostate cancer.*

Prescription Use __X___ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ____. (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)

Reena Philip

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

510(k) k103502