NOV 2 4 2003

510(k) Summary

Date prepared **1/21/03.**

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92 (c).

The assigned 510(k) number is K030263.

The submitter of this premarket notification is Immunicon Corporation, 3401 Masons Mill Road, Suite 100, Huntingdon Valley, PA 19006. The official correspondent is Peter J Scott, Vice President of Quality Assurance and Regulatory Affairs (215-830-0777 ext 235, fax 215-830-0751).

The subjects of this summary of Safety and Effectiveness are the Immunicon *CellTracks*™ System. The predicate devices are the Becton Dickinson FACSCalibur System. The subject devices are intended for use in traditional Clinical laboratories and Research Institutions. The common and classification name for this instrument is an Automated Differential Cell Counter.

The intended use for the Immunicon *CellTracks*™ System is as a general-purpose laboratory bench top scanning cytometer designed to enumerate fluorescently labeled leukocyte subsets that are immuno-magnetically selected and aligned. The system is for *in vitro* diagnostic use.

The CellTracks Analyzer is used in conjunction with reagents containing ferrofluids and fluorescent conjugates. Depending on the application, samples may be prepared manually or using the CellTracks AutoPrep Sample Preparation System. Ferrofluid consists of a magnetic core surrounded by a polymeric layer coated with antibodies for capturing cells. Ferrofluid particles are colloidal (25-100 nanometers in radius) and when mixed with a sample containing target cells, the antibodies bound to the ferrofluid bind the associated antigens to the target cells. Fluorescent reagents are added for the identification and the enumeration of the target cells. The ferrofluid/sample mixture is placed in a magnetic field (Magnest), to select and align the labeled target cells.

The Magnest, containing the fluorescence-labeled magnetically aligned target cells, is placed on the CellTracks analyzer and is ready for analysis.

Discussion of Clinical and nonclinical testing

A Clinical study was performed using blood samples from 149 HIV+ patients and 150 samples obtained from normal donors to determine CD3 and CD4 lymphocyte counts. The samples were obtained from three geographically dispersed sites and Medical Technologists performed testing according to NCCLS EP9-A, Method Comparison and Bias Estimation Using Patient Samples. The samples were analyzed using three *CellTracks*™ Analyzers and compared with results of the Becton Dickinson FACSCalibur™ System. Results of the testing indicated a slope of 0.95 and an R^2 of 0.9802 for CD4 and a slope of 0.77 and an R^2 of 0.9375 for CD3.

Nonclinical testing included linearity, precision, and the affects of interfering substances. The CellTracks Analyzer demonstrated linearity from 0 to 2,000 cells/ul. A 20-day precision study was performed according to NCCLS Guideline EP5-A, Evaluation of Precision Performance of Clinical Chemistry Devices using three CellTracks™ Analyzers and BD Multi-Check Controls. The normal CD3 control (1086 cells/ul) within-run CV's ranged from 3.68% to 4.34%. For the low CD3 control (505cells/ul), within run CV's ranged from 3.89% to 6.60%. The potential affects of interfering substances was tested using lipid levels from 0 to approximately 5,000 mg/dL, hematocrits from 43.3 to 76.2%, platelet counts from 210 x 10^3 to 2,040 x 10^3, white blood cell counts of 4.1 x 10^3 to 25.0 x 10^3 and free hemoglobin in plasma levels of 10.3 to 12.4 g/dL, none of the interfering substances utilized had an adverse affect on the CD3 or CD4 counts obtained.

The *CellTracks* ™ Analyzer was tested and met the applicable requirements of IEC 61326-1998 "Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements and IEC 601010-2-101 "Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment". The CellTracks Analyzer meets the requirements of 21 CFR part 1040.10 laser products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 4 2003

Mr. Peter Scott
Vice President, Quality Assurance
and Regulatory Affairs
Immunicon Corporation
3401 Masons Mill Road, Suite 100
Huntingdon Valley, Pennsylvania 19006

Re: k030263
Trade/Device Name: Immunicon *CellTracks*™ Analyzer
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ
Dated: January 24, 2003
Received: January 27, 2003

Dear Mr. Scott:

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 either class II (Special Controls) or class III (PMA), 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); 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Immunicon *CellTracks*™ Analyzer

Indications For Use:

To enumerate fluorescently labeled leukocyte subsets that are immuno-magnetically selected and aligned.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K030263

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)