MAR 1 2 2004

510(k) Summary

Date prepared: January 8, 2004

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

The assigned 510(k) number is K040077.

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 subject of this summary of Safety and Effectiveness is the Immunicon CellTracks™ AutoPrep System. The predicate device is the Immunicon CellPrep™ Sample Preparation system. The subject device is intended for use in traditional Clinical laboratories and Research Institutions. The common and classification name for this device is an Automated Blood Cell Diluting Apparatus.

The intended use for the Immunicon CellTracks™ AutoPrep System is as 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, CellSpotter™ System, flow cytometers or microscopes may be used for cell identification and enumeration. The system is for *in vitro* diagnostic use.

The CellTracks™ AutoPrep System is an automated sample-handling instrument that starts with a tube of anticoagulated whole blood and delivers an enriched, processed sample that is ready to analyze by flow-cytometry, fluorescent microscopy, CellSpotter™ System or by the CellTracks™ Analyzer. The AutoPrep System performs several steps, including red cell detection, plasma aspiration and filling of a sample chamber or test tube. The principal of operation relates to the addition of a ferrofluid, which has been conjugated with monoclonal antibodies that act with the system to magnetically separate the cells of interest and in subsequent steps, within the system, to add fluorescence-labeled monoclonals to further differentiate the captured cells. The first reagent added is

ferrofluid, which consists of a magnetic core surrounded by a protein layer coated with antibodies for attachment to cells. Ferrofluid particles are colloidal and when mixed with a sample containing the target cells, they interact and attach to the target cells. The ferrofluid/sample mixture is placed in a strong magnetic field, which causes the labeled target cells to move to the side of the tube. The blood is aspirated, the magnetic field is removed and the cells are resuspended in a small volume of buffer and fluorescent reagents are added for the identification and enumeration of the target cells. Another magnetic separation step and resuspension is performed and the sample is now ready for analysis. The immunomagnetic enrichment process is the new technology but does not raise any new issues of safety and effectiveness.

Discussion of Clinical and nonclinical testing

Medical or Laboratory Technicians performed clinical testing at three clinical sites. The Clinical trial consisted of performing a 20 day precision study according to NCCLS "EP5-A Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline". The Clinical trial indicated that the CellTracks™ AutoPrep System was capable of removing small numbers of control cells reproducibly from 7.5 ml of whole blood (38 cell spike level CV = 16.8, 264 spike level CV = 11.72).

Nonclinical testing indicated a sensitivity of being able to recover cells at very low levels at approximately one cell per a 7.5 ml volume of whole blood and a linear recovery range from 2 to 906 cells with a slope of 1.0221 and an $r^2 = 0.9946$. A method comparison was performed comparing the AutoPrep system to the predicate device according to NCCLS "EP9-A Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline" The results of the comparison showed a correlation coefficient of 0.99, a slope of 1.0935 with an intercept of 4.0344 and an r^2 of 0.9801.

The CellTracks AutoPrep™ System was tested and met the requirements of EN 61326-1, meets class A, conforms to EU EMC Directive. Tested to FCC CFR 47, Part 15, subpart B, meets Class A. Tested to UL61010A, CSA C22.2 No. 1010-1 and EN61010. UL listed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 2 2004

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

Re: k040077
Trade/Device Name: Immunicon CellTracks™ AutoPrep System
Regulation Number: 21 CFR § 864.5240
Regulation Name: Automated blood cell diluting apparatus
Regulatory Class: I
Product Code: GKH
Dated: January 8, 2004
Received: January 14, 2004

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,

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K040077

Device Name: CellTracks AutoPrep System

Indications For Use:

The intended use for the Immunicon CellTracks™ AutoPrep System is as 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, CellSpotter™ System, flow cytometers or microscopes may be used for cell identification and enumeration. The system is for *in vitro* diagnostic use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

√ In Vitro diagnostic use

Prescription use X

(Optional Format 3-10-98)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040077