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1C030596

510(k) Summary

Date prepared August 5, 2003.

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

The assigned 510(k) number is k030596.

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 *CellSave*™ Preservative Tube. The predicate device is the Becton Dickinson Vacutainer Brand Blood Collection Tube with EDTA Anticoagulant. The Immunicon CellSave Preservative Tube is intended for the collection and preservation of circulating epithelial cells (tumor cells) and mature human T lymphocytes (CD3+) and helper/inducer (CD3+/CD4+) T lymphocyte subsets in whole blood, to be used for enumeration and phenotyping. The device is for *in vitro* diagnostic use.

The *CellSave*™ tube is an evacuated closed glass tube for collecting, transporting and processing blood. The assembly consists of a rubber stopper, a glass tube and anticoagulant. The anticoagulant contains EDTA (disodium EDTA), polyethylene glycol and a preservative reagent.

NONCLINICAL TESTING

The *CellSave*™ Sample Tube was tested and met the applicable requirements of ISO 6710 Single Use containers for venous blood specimen collection and NCCLS Standard H1-A4 Evacuated Tubes and Additives for Blood Specimen Collection-Fourth Edition; Approved Standard.

Studies indicated that within a couple of hours epithelial cell counts decreased significantly when preserved in EDTA alone. It was also observed that separation of leukocyte sub-populations identified by cell surface antigens as measured by flow cytometry decreased over time. The use of the preservative contained within the *CellSave*™ tube preserved circulating epithelial cells for 72 hours and maintained the separation of the leukocyte sub-populations for 24 hours.

PERFORMANCE

Recovery

Recovery was evaluated by spiking samples with low tumor cell numbers (0, 50, 100, and 200 cells/7.5 ml) and high tumor cell numbers (0, 100, 1000, and 10,000 cells/7.5 ml). Blood from 5 normal donors was collected into CellSave tubes and spiked with SKBR-3 cells (a breast cancer cell line). Samples were processed and stained with a nucleic acid dye, anti-CD45-APC and anti-CK-PE using the CellPrep™ Semi-Automated Processing System and analyzed using a FACSCalibur flow cytometer with beads to enable calculation of absolute counts of cells. For the low spike experiment, the regression equation was y=0.8x+4.7 and the R^2=0.98. For the high spike experiment, the regression equation was y=0.9x+6.2 and the correlation was R^2=0.99.

	Low spike				High Spike			
Donor	**0**	**50**	**100**	**200**	**0**	**100**	**1,000**	**10,000**
A	2	31	89	164	2	84	876	8,259
B	2	44	97	141	4	74	775	8,185
C	5	51	92	175	1	75	880	9,342
D	1	46	81	153	2	118	846	8,030
E	4	52	82	181	2	106	959	9,014
Mean	3	45	88	163	2	91	867	8,566
% Recovery		89.3%	88.2%	81.4%		91.3%	86.7%	85.7%

Interfering substances

Blood from 5 normal donors was collected into EDTA and *CellSave*™ tubes and spiked with approximately 800 SKBR-3 cells. *CellSave*™ tubes were spiked with potential interfering substances (hemolysis 5+, lipemia 1.94-2.04% emulsified fat, icteris 7.0 mg/dl) to determine the effect on recovery and enumeration of tumor cells. Duplicate samples were processed using CellPrep™ Semi-Automated Sample Processing System and analyzed using the FACSCalibur flow cytometer.

Donor	EDTA Control			CellSave™ Control		
	# Cells Recovered	# Cells Spiked	% Recovery	# Cells Recovered	# Cells Spiked	% Recovery
A1	452	828	55%	388	696	56%
A2	445	828	54%	486	696	70%
B1	802	749	107%	689	696	99%
B2	711	749	95%	690	696	99%
C1	580	771	75%	289	716	40%
C2	451	771	58%	272	716	38%
D1	571	771	74%	552	716	77%
D2	642	771	83%	636	716	89%
E1	610	771	79%	526	716	73%
E2	541	771	70%	535	716	75%
Mean	581		75%	506		72%
SD	117		17%	150		22%

Donor	CellSave™, Hemolysis			CellSave™, Lipemia			CellSave™, Icteris		
	# Cells Recovered	# Cells Spiked	% Recovery	# Cells Recovered	# Cells Spiked	% Recovery	# Cells Recovered	# Cells Spiked	% Recovery
A1	482	696	69%	664	696	95%	638	696	92%
A2	502	696	72%	691	728	95%	612	728	84%
B1	514	696	74%	748	696	107%	678	696	97%
B2	571	696	82%	712	696	102%	679	696	98%
C1	499	716	70%	568	716	79%	561	716	78%
C2	470	716	66%	599	716	84%	514	716	72%
D1	582	716	81%	628	716	88%	651	716	91%
D2	551	716	77%	549	716	77%	589	716	82%
E1	571	716	80%	620	716	87%	554	716	77%
E2	499	716	70%	620	716	87%	584	716	82%
Mean	524		74%	640		90%	606		85%
SD	41		6%	63		10%	55		9%

Hemolysis, lipemic and icteric whole blood samples collected into the *CellSave*™ tube do not interfere with the recovery and enumeration of tumor cells.

CLINICAL TESTING

A Clinical study was performed at Immunicon using blood samples obtained from five geographically dispersed sites from 102 metastatic cancer patients providing 107 blood specimens for analysis. Seventy of these specimens had sufficient blood volume for testing at approximately 24 hours and again at approximately 96 hours. Initial circulating epithelial cell (tumor cell, or CTC) counts ranged from 0 to 640 CTC per sample. Twenty-one of these specimens had an average of greater than or equal to 3 CTC at the two testing time points. The linear correlation for CTC recovery over this time period comparing 24 hours to 96 hours was an R^2 equal to 1.00 with a regression equation of $y=1.1x-7.1$. A Wilcoxon signrank test indicated that the CTC counts obtained at 24 hours and those obtained at 96 hours were not significantly different ($p > 0.90$). These data demonstrate that the recovery of circulating epithelial cells from whole blood remains stable over a 72 hour time period using the *CellSave*™ blood collection tube.

A second clinical study was performed to compare CD3/CD4 immunophenotyping over a 72 hour time period using both EDTA and *CellSave*™ tubes. Whole blood samples were obtained from fifty healthy volunteers and twelve patients with confirmed HIV. Results of CD3/CD4 testing on days 1, 2, and 3 resulted in R^2values during the three days of between 0.97 and 0.98 and slopes of 0.91 to 0.97.

Together, these studies demonstrate that the *CellSave*™ blood collection tube is effective in preserving T lymphocytes and epithelial cells for phenotyping and enumeration over a 72 hour time period. The numbers of CD3 and CD4 positive lymphocytes and epithelial cells are unchanged over a 72-hour period. Preservation of T lymphocytes and their antigens are also effective using different instruments for enumeration of labeled cells, which demonstrates that the *CellSave*™ tube is useful across multiple instruments.

These studies justify the use of the CellSave tube for drawing, shipping and storing venous blood up to 72 hours for the counting and immunophenotyping of epithelial cells and leukocytes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 8 2003

Mr. Peter J. Scott
Vice President of Quality Assurance
and Regulatory Affairs
Immunicon® Corporation
3401 Masons Mill Road – Suite 100
Huntingdon Valley, PA 19006

Re: k030596
Trade/Device Name: The Immunicon CellSave™ Preservation Tube
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: June 3, 2003
Received: June 4, 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): K030596

Device Name: The Immunicon CellSave™ Preservation Tube

Indications For Use:

CellSave tubes are evacuated blood collection tubes that are designed to be used with standard phlebotomy supplies for venous blood collections. The tube contains 300µl of a solution that contains Na_2EDTA and a cell preservative. The preservative preserves morphology and cell surface antigen expression of the epithelial cells and leukocytes. This tube may be used for monitoring of circulating epithelial cells (tumor cells) which may aid in the management of cancer patients. This tube may be used for monitoring CD3+/CD4+ T lymphocyte subsets which may aid in the management of patients with HIV/AIDS.

✓ prescription use

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K030596

(Optional Format 3-10-98)