

January 14, 2002

510(K) SUMMARY

Cylex Inc. Immune Cell Function Assay

Submitted by:

Cylex Inc.
8980-I Old Annapolis Road
Columbia, MD 21045

K101911

OCT 18 2010

Contact:

Dr. Judy Britz

Name of Device:

Trade Name: Immune Cell Function Assay
Common Name: CD4 Cell Stimulation Assay
Classification Name: Automated Differential Cell Counter

Predicate Device:

Becton Dickinson TriTest™ CD4 FITC/CD8 PE/CD3
PerCP Reagent;
Becton Dickinson MultiTest™ CD3 FITC/CD8 PE/CD45
PerCP/CD4 APC Reagent

Device Description:

Intended Use: The **Cylex Immune Cell Function Assay** measures the concentration of ATP from circulating CD4 cells following in vitro stimulation with phytohemagglutinin (PHA) as an indicator of immune cell function. This measurement is made on heparin anti-coagulated whole blood using a luminometer and luciferin/luciferase. The assay is used for the detection of cell mediated immune response in populations undergoing immunosuppressive therapy for organ transplant.

Test Description The **Cylex Immune Cell Function Assay** detects cell-mediated immunity in whole blood after a 15-18 hour incubation with stimulant. During incubation, increased ATP synthesis occurs within the cells that respond to the stimulant phytohemagglutinin (PHA). Concurrently, whole blood is incubated in the absence of stimulant for the purpose of assessing basal ATP activity. Anti-CD4 monoclonal antibody coated magnetic particles are added to immunoselect CD4 cells from both the stimulated and non-stimulated wells. After washing the selected CD4 cells on a magnet tray, Lysis Reagent is added to release intracellular ATP. Addition of Luminescence Reagent (luciferin/luciferase) to the released ATP produces light according to the following equation:



The amount of light measured by a luminometer (emission maximum 562 nm) is proportional to the concentration of ATP. The concentration of ATP (ng/mL) is calculated from a calibration curve and compared to ATP level ranges to characterize the cellular immune function of the sample.

510(K) SUMMARY

Cylex Inc. Immune Cell Function Assay (cont.)

Substantial Equivalence:

The **Cylex Inc. Immune Cell Function Assay** has been found to be substantially equivalent to the Becton Dickinson TriTest™ CD4 FITC/CD8 PE/CD3 PerCP Reagent (K971205) and MultiTest™ CD3 FITC/CD8 PE/CD45 PerCP/CD4 ACP Reagent (K974360). All assays differentiate CD4 cells; the Cylex assay determines the responsiveness of those cells and the Becton Dickinson assays count the number of those cells.

A multi-center study was conducted on freshly drawn blood collected from 44 apparently healthy adults and 78 transplant recipients (17 at discharge from the hospital and 61 post-discharge follow-up). The samples were evaluated with the Cylex Immune Cell Function Assay. The apparently healthy adult population consisted of 11% (5) females, 86% (38) males and 3% (1) unknown, with an age range of 20 - 60 years. The ethnicity of the population was 80% (35) African American, 16% Caucasian (7), and 4% (2) other or unknown. The transplant population consisted of 33% (26) females and 67% (52) males, with an age range of 20 - 64 years. The ethnicity of the population was 15% (12) African American, 74% Caucasian (58), 10% (8) other or unknown. The organs transplanted were 55% (43) liver, 36% (28) kidney, 4% (3) pancreas, and 5% (4) multiple organs.

The means of the two populations were found to be statically different; the results are summarized in the following table.

Population	Apparently Healthy	Transplant
Cylex Inc. Immune Cell Function Assay	n = 44	n = 78
ATP Results		
Mean / SD (ng/mL)	449 / 152	274 / 166
Median (ng/mL)	430	251
Range (ng/mL)	205 – 967	21 – 759
Becton Dickinson Total CD4 count by Flow Cytometry	n = 44	n = 78
Mean / SD (ng/mL)	786 / 490	487 / 403
Median (ng/mL)	654	389
Range (ng/mL)	130 – 2659	<68 - 1904

Patient Status	Transplant Subjects	Normal Subjects	Total
Immune cell functions assay result ≤260	41	4	45
Immune cell function assay result >260	37	40	77
Total	78	44	122

Patient Status	Transplant Subjects	Normal Subjects	Total
Total CD4 count ≤350	33	5	38
Total CD4 count >350	45	39	84
Total	78	44	122

*U.S. Patent No. 5,773,232



Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Cylex Inc.
c/o Ms. Judi Smith
President, Judi Smith LLC
8980 I Old Annapolis Road
Columbia, MD 21045

OCT 18 2010

Re: k101911

Trade/Device Name: Immuknow® Immune Cell Function Assay
Regulation Number: 21 CFR§864.5220
Regulation Name: Automated Differential cell counter
Regulatory Class: Class II
Product Code: NID
Dated: August 20, 2010
Received: September 1, 2010

Dear Ms. Smith:

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.

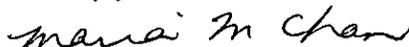
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Devices and Radiological Health

Enclosure

Indication for Use

K101911

510(k) Number (if known): K101911

OCT 18 2010

Device Name: Immune Cell Function Assay

Indication For Use:

ImmuKnow[®]-the Cylex[®]™ Immune Cell Function Assay measures the concentration of ATP from circulating CD4 cells following in vitro stimulation with phytohemagglutinin (PHA) as an indicator of immune cell function. This measurement is made on heparin anti-coagulated whole blood using a luminometer and luciferin/luciferase. The assay is used for the detection of cell mediated immune response in populations undergoing immunosuppressive therapy for organ transplant.

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)

Deena Philip

Division Sign-Off
Office of Device Evaluation

510(k) k101911