act). Thus, the definition of a class II device was changed from ''performance standards'' to ''special controls.'' In order for a device to be reclassified from class II to class I, the agency must determine that special controls are not necessary to provide reasonable assurance of its safety and effectiveness.

III. Background

In the **Federal Register** of July 16, 1982 (47 FR 31130), FDA issued a final rule classifying the breathing frequency monitor into class II (§ 868.2375). The preamble to the proposal to classify the device included the recommendation of the Anesthesiology Device Panel. The Panel identified the following risks to health associated with the use of the devices: (1) Failure of the device or alarm may cause abnormal conditions to go undiscovered and result in serious patient injury or death and (2) if the device does not monitor the patient's breathing frequency accurately he/she may receive incorrect therapy.

In the **Federal Register** of September 4, 1979 (44 FR 51726), FDA issued a final rule classifying the electroencephalograph into class II (§ 882.1400 (21 CFR 882.1400)). The preamble to the proposal to classify the device included the recommendation of the Neurological Device Panel. The Panel's recommendation identified the following risks to health associated with use of the device: (1) Misuse of the device as a result of using untrained persons may result in improper diagnosis and treatment; (2) misdiagnosis of the physiological symptoms could cause a misdiagnosis and lead to improper treatment of the patient's neurological condition; and (3) electrical shock could be associated with current leakage of the device, making it hazardous because the device makes a low resistance contact with the patient.

On August 18, 2004, IM Systems submitted three petitions requesting FDA to reclassify the SleepCheck device, the ActiTrac, and PAM–RL devices from class II to class I (Ref. 1). Under 21 CFR 860.120(b) the reclassification of any device within a generic type of device causes the reclassification of all substantially equivalent devices within that generic type of device.

IV. Device Description

The SleepCheck device is classified within the generic type of device called the breathing frequency monitor (§ 868.2375). FDA identifies the breathing frequency monitor as a device intended to measure or monitor a patient's respiratory rate. The device may provide an audible or visible alarm when the respiratory rate, averaged over time, is outside operator settable alarm limits.

The ActiTrac and PAM–RL devices are classified within the generic type of device called the electroencephalograph (§ 882.1400). FDA identifies the electroencephalograph as a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.

V. FDA's Decision

After reviewing both the reclassification petitions and the petitioner's responses to our subsequent requests for information, FDA has found that the petitions do not contain any valid scientific evidence to support a conclusion that general controls would provide reasonable assurance of the devices' safety and effectiveness for their intended uses or that special controls are not necessary to provide reasonable assurance of the safety and effectiveness of the devices. Therefore, FDA is denying the petitions for reclassification of these device types.

VI. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. These references may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petitions from IM Systems for the reclassification of the SleepCheck device, PAM–RL device, and the ActiTrac device, dated August 18, 2004.

Dated: July 5, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–11115 Filed 7–13–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Method for Expanding Allodepleted Antigen Specific T Cells

Description of Technology: Available for licensing and commercial development are methods of producing a population of purified non-alloreactive antigen-specific T cells that recognize an antigen of interest. Thus, the population of donor T cells can be used to produce immune response against the antigen of interest (e.g., cytomegalovirus) in a recipient without producing an immune response to the recipient. Currently available methods for isolating and expanding antigen-specific T cells can be inefficient and produce populations of cells that include donor-reactive T cells. The present method enables rapid production of populations of T cells that recognize an antigen of interest but are depleted for alloreactive T cells: A population of donor T cells is contacted with a population of irradiated recipient antigen presenting cells (T–APCs) to produce a population of alloreactive T cells. The alleractive T cells are removed by purification with an antibody that specifically binds a cell surface marker (e.g., CD25, CD69, CD38 or CD71). The population of allo-depleted donor cells is then contacted with donor T antigen presenting cells (T–APCs) expressing an antigen of interest and produces a population of donor allo-depleted activated CD4 and CD8 T cells.

Applications: Immune response to opportunistic infectious in immuno-compromised transplant or graft recipients.

Market: (1) Cytomegalovirus; (2) General post-transplant opportunistic infections.

Inventors: J. Joseph Melenhorst and A. John Barrett (NHLBI).

Publications:

1. JJ Melenhorst, TH Brummendorf, M Kirby, PM Lansdorp, AJ Barrett. ''CD8+T cells in large granular lymphocyte

leukemia are not defective in activation- and replication-related apoptosis.'' Leuk Res. 2001 Aug;25(8):699–708.

2. H Fujiwara, JJ Melenhorst, F El Ouriaghli, et al.''In vitro induction of myeloid leukemia-specified CD4 and CD8 T cells by CD40 ligand-activated B cells gene modified to express primary granule proteins.'' Clin Cancer Res. 2005 Jun 15;11(12):4495–4503.

Patent Status: U.S. Provisional Application No. 60/804,404 filed 09 Jun 2006 (HHS Reference No. E–136–2006/0–US–01).

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Michael A. Shmilovich, Esq.; 301/435–5019; *shmilovm@mail.nih.gov*.

Collaborative Research Opportunity: The NHLBI Hematology Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize a Method for Expanding Allodepleted Antigen Specific T Cells. Please contact Dr. A.J. Barrett at 301/402–4170 or *barrettjj@mail.nih.gov* for more information.

A Newly Discovered Bacterium in the Family Acetobacteraceae

Description of Technology: Available for licensing and commercial development is a newly discovered bacterium in the Acetobacteraceae family. This bacterium was isolated, characterized and grown from lymph nodes of a patient with chronic granulomatous disease (CGD), a rare genetic disorder that impairs the immune system.

This Gram-negative bacterium is an aerobic, faculatitive methylotroph that produces yellow pigmented colonies. The closest nucleic acid sequence match was to Gluconacetobacter sacchari (95.7% similarity) of the acetic acid bacteria. The newly descibed bacterium belongs to a new genus and species in the Acetobacteraceae family and was named Granulibacter bethesdenis. Acetobacteraceae are characterized by their ability to convert alcohol (ethanol) to acetic acid in the presence of air. Members of this family are used industrially in the production of vinegar, and are encountered during fermentation of wine.

G. bethesdenis can breakdown methanol, formaldehyde, ethanol and their intermediate breakdown products into non-toxic end-products. Examples of non-toxic end-products include carbon dioxide, water, and acetic acid.

The invention provides the complete genome sequence from the bacterium. Also included are permission to purify and utilize unique enzymes that the bacteriuum uses to degrade organic materials, for example methanol dehydrogenase, formaldehyde-activating enzyme, and methylenetetrahydrofolate dehydrogenase (NAPD+).

Applications: (1) Biodegradation of organic waste; (2) Microbial fuel cell; (3) Production of purified polypeptide enzymes for industrial use.

Inventors: Steven M. Holland (NIAID), Patrick Murray (CC), Adrian M. Zelazny (CC), David E. Greenberg (NIAID).

Publication: DE Greenberg, L Ding, AM Zelazny, F Stock, A Wong, et al. ''A novel bacterium associated with lymphadenitis in a patient with chronic granulomatous disease.'' PLoS Pathog 2006 Apr;2(4):e28. Epub 2006 Apr 14, doi: 10.1371/journal.ppat.0020028. (PubMed abstract = *http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=16617373&query_hl=1&itool=pubmed_docsum*).

Patent Status: U.S. Provisional Application No. 60/788,521 filed 31 Mar 2006 (HHS Reference No. E–083–2006/0–US–01).

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Chekesha Clingman, PhD.; 301/435–5018; *clingmac@mail.nih.gov*

Collaborative Research Opportunity: The NIAID Laboratory of Host Defenses is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Kelly Murphy at 301–451–3523 or *murphykt@niaid.nih.gov* for more information.

Fluorescent Imaging and Photodynamic Treatment of Tumors

Description of Technology: Available for licensing and commercial development are methods and compositions for optically detecting tumors, in particular disseminated intraperitoneal cancers. Unlike exiting detection methods using avidin and/or galactosyl serum albumin (GSA), the current invention allows tumors to be visualized *in situ*, with high sensitivity and without hazardous radioactive probes. The invention also provides methods of treating tumors.

The invention describes the labeling of avidin and GSA with fluorophores. The fluorescently labeled agents selectively bind to cells expressing asialoglycoprotein receptors on the surface of tumor cells, such as in tumors of the ovary, stomach, colon or pancreas. Metastatic tumor cells can then be detected endoscopically, laparoscopically, or during surgery with an appropriate imaging system.

The fluorescently labeled avidin and GSA can be used diagnostically, but also have an application for treating cancer. Using photoactivatable fluorophores linked to avidin or GSA, free radicals can be produced which results in localized death of tumor cells upon exposure to excitation with the appropriate wavelength.

Applications: (1) Optical detection of tumor cells and metastatic nodules; (2) Photodynamic treatment of tumors.

Inventors: Hisataka Kobayashi and Peter Choyke (NCI).

Patent Status: U.S. Provisional Application No. 60/751,429 filed 16 Dec 2005 (HHS Reference No. E–335–2005/0–US–01).

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Chekesha Clingman, PhD; 301/435–5018; *clingmac@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute *Molecular Imaging Program* is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize tumor specific imaging agents. Please contact Laurie Zipper, Ph.D., at 301–594–4650 or *zipperl@mail.nih.gov* for more information.

Coacervate Microparticles Useful for the Sustained Release Administration of Therapeutics Agents

Description of Technology: The described technology is a biodegradable microbead or microparticle, useful for the sustained localized delivery of biologically active proteins or other molecules of pharmaceutical interest. The microbeads are produced from several USP grade materials, a cationic polymer, an anionic polymer and a binding component (e.g., gelatin, chondroitin sulfate and avidin), in predetermined ratios. Biologically active proteins are incorporated into preformed microbeads via an introduced binding moiety under nondenaturing conditions.

Proteins or other biologically active molecules are easily denatured, and once introduced into the body, rapidly cleared. These problems are circumvented by first incorporating the protein into the microbead. Microbeads with protein payloads are then introduced into the tissue of interest, where the microbeads remain while degrading into biologically innocuous materials while delivering the protein/drug payload for adjustable periods of

time ranging from hours to weeks. This technology is an improvement of the microbead technology described in U.S. Patent No. 5,759,582.

Applications: This technology has two commercial applications. The first is a pharmaceutical drug delivery application. The bead allows the incorporated protein or drug to be delivered locally at high concentration, ensuring that therapeutic levels are reached at the target site while reducing side effects by keeping systemic concentration low. This microbead accomplishes this while protecting the biologically active protein from harsh conditions traditionally encountered during microbead formation/drug formulation.

The microbeads are inert, biodegradable, and allow a sustained release or multiple-release profile of treatment with various active agents without major side effects. In addition, the bead maintains functionality under physiological conditions.

Second, the microbead and microparticles can be used in various research assays, such as isolation and separation assays, to bind target proteins from biological samples. A disadvantage of the conventional methods is that the proteins become denatured. The denaturation results in incorrect binding studies or inappropriate binding complexes being formed. The instant technology corrects this disadvantage by using a bead created in a more neutral pH environment. it is the same environment that is used for the finding of the protein of interest as well.

Inventor: Phillip F. Heller (NIA).

Patent Status: U.S. Provisional Application No. 60/602,651 filed 19 Aug 2004 (HHS Reference No. E–116–2004/0–US–01); PCT Application No. PCT/US2005/026257 filed 25 Jul 2005, which published as WO 2006/023207 on 02 Mar 2006 (HHS Reference No. E–116–2004/0–PCF–02).

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Susan O. Ano, Ph.D.; 301–435–5515; *anos@mail.nih.gov.*

Methods and Compositions Related to GHS–R Antagonist

Description of Technology: This invention describes that additional functional role for D–Lys3 GHRP–6 (a known GHS–R antagonist, peptide) as a blocker of two well-known chemokine receptors, namely CCR5 and CXCR4. These receptors are major HIV co-receptors and are critical for HIV binding, fusion and entry into human T cells, monocytes, dendritic cells, and various other cells within the body. Moreover, these receptors and their ligands play a major role in inflammation and a variety of acute and chronic disease states. Overall, these two mammalian chemokine receptors are currently major drug targets for treatment of AIDS, cancer and many immunoregulatory disorders. Many identified antogonists block one or the other receptor. Since D–Lys3 GHRP–6 actually binds and blocks both these chemokines receptors at the same time hindering their activity and HIV infectivity, D–Lys3 GHRP–6 may be a good therapeutic candidate for treatment of AIDS and inflammatory diseases.

Inventors: Vishwa D. Dixit and Dennis D. Taub (NIA).

Patent Status: U.S. Provisional application No. 60/773,076 filed 13 Feb 2006 (HHS Reference No. E–017–2004/0–US–01).

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Sally Hu, Ph.D., M.B.A.; 301–435–5605; *hus@od.nih.gov.*

Collaborative Research Opportunity: The National Institute on Aging's Laboratory of Immunology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Nicole D. Guyton at 301–435–3101 or *darackn@mail.nih.gov* for more information.

Dated: July 3, 2006

David R. Sadowski,

Acting Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 06–6211 Filed 7–13–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of a meeting of the Advisory Committee to the Director, National Cancer Institute.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Director, National Cancer Institute.

Date: August 9, 2006

Time: 1 p.m. to 2 p.m.

Agenda: Review of Adolescent and Young Adult Oncology Progress Review Group Report.

Place: National Institutes of Health, Building 31, Room 11A48, 31 Center Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Cherie Nichols, Director of Science Planning and Assessment, National Cancer Institute, Building 6116, Room 205, Bethesda, MD 20892, (301) 496–5515.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's home page: deainfo.nci.nih.gov/advisory/joint/htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS).

Dated: July 7, 2006.

Anna Snouffer,

Acting Director, Office of Federal advisory Committee Policy.

[FR Doc. 06–6204 Filed 7–13–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which could constitute a clearly unwarranted invasion of personal privacy.