SEP 1 8 2009

510K SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21 CFR 807.92

The assigned 510(k) number is: K090810

COMPANY/CONTACT PERSON

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DATE PREPARED

August 30, 2009

DEVICE NAME

Trade Name: Thermo Scientific Cyto-Cal™ Count Tubes

Common Name: Cyto-Cal™ Count Tubes

Device Classification: Automated Differential Cell Counter

Regulation number: 21 CFR 864.5220

Product Code: GKZ

INTENDED USE

Thermo Scientific Cyto-Cal™ Count Tubes are used for determining absolute counts of leucocytes in blood.
Thermo Scientific Cyto-Cal™ Count Tubes are used with the immunophenotyping reagents BD TriTEST™, flow cytometers BD FACS Calibur or BD FACS Canto, and software BD CellQuest or DIVA. Thermo Scientific Cyto-Cal™ Count Tubes can be used with the BD FACS™ Loader. This in vitro diagnostic device is intended for clinical use only.

SUBSTANTIALLY EQUIVILANT PREDICATE DEVICE

Thermo Scientific Cyto-Cal™ Count Tubes are substantially equivalent to the previously cleared BD Trucount Tubes (K965053)

DESCRIPTION OF DEVICE

Thermo Scientific Cyto-Cal™ Count Tubes contain uniform 5.4 µm microspheres encapsulated with three dyes. The single tube contains fluorescent beads that have equivalent emissions to multiple channels for FITC, PE, Per-CP, PE-Cy5, APC. Each tube contains known number of fluorescent particles as indicated on the product label.

PRINCIPLES OF THE PROCEDURE

Procedures described herein apply to immunophenotyping of lymphocytes. In the procedure, the cell typing monoclonal antibody reagent and whole blood is added directly to the Cyto-Cal™ Count Tube. The dried pellet in the tube dissolves, releasing a known number of fluorescent beads. During analysis, the absolute number (cells/µL) of positive cells in the sample can be determined by comparing cellular events to bead events. If you are manually performing data analysis, simply divide the number of positive cellular events by the number of bead events, and then multiply by the Cyto-Cal Count bead concentration. The cell typing or immunophenotyping of lymphocytes is effectively used in monitoring immune response or in determining a particular cell count.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Comparison	Predicate Device – BD Trucount Tubes	Thermo Scientific Cyto-Cal™ Count Tubes
Intended Use	BD Trucount Tubes are used for determining absolute counts of leucocytes in blood. BD Trucount Tubes are designed for use with in vitro diagnostic products such as BD TriTEST™ reagents, and a suitably equipped flow cytometer. BD Trucount Tubes can be used with the BD FACS™ Loader.	Thermo Scientific Cyto-Cal™ Count Tubes are used for determining absolute counts of leucocytes in blood. Thermo Scientific Cyto-Cal™ Count Tubes are used with the immunophenotyping reagents BD TriTEST™, flow cytometers BD FACS Calibur or BD FACS Canto, and software BD CellQuest or DIVA. Thermo Scientific Cyto-Cal™ Count Tubes can be used with the BD FACS™ Loader. This in vitro diagnostic device is intended for clinical use only.
Test Principle	Add the cell typing monoclonal antibody reagent and whole blood directly to the BD Trucount Tubes. The lyophilized pellet in the tube dissolves, releasing a known number of fluorescent beads. During analysis, the absolute number (cells/µL) of positive cells in the sample can be determined by comparing cellular events to bead events. If the appropriate software, such as BD MultiSET™, is used, absolute counts will be determined by the software. If you are manually performing data analysis using software such as BD CellQuest™, simply divide the number of positive cellular events by the number of bead events, then multiply by the BD Trucount bead concentration.	Add the cell typing monoclonal antibody reagent and whole blood directly to the Thermo Scientific Cyto-Cal™ Count Tubes. The dried pellet in the tube dissolves, releasing a known number of fluorescent beads. During analysis, the absolute number (cells/µL) of positive cells in the sample can be determined by comparing cellular events to bead events. If the appropriate software, such as BD MultiSET™, is used, absolute counts will be determined by the software. If you are manually performing data analysis using software such as BD CellQuest™, divide the number of positive cellular events by the number of bead events, then multiply by the Thermo Scientific Cyto-Cal™ Count bead concentration.

Matrix	Freeze-dried pellet of fluorescent beads in a single-use tube.	Dried pellet of fluorescent beads in a single-use tube.
Reagents	Each pouch contains 25 BD Trucount Tubes, sufficient for 25 tests.	Each package contains 25 Thermo Scientific Cyto-Cal™ Count Tubes, sufficient for 25 tests.
Instrument	Flow cytometer	Flow cytometer
Storage Condition	2 to 25 °C	20 to 25 °C
Particle Concentration	~50,000/tube	~50,000/tube
Lysing reagent	FACSLyse	FACSLyse

SUMMARY OF CLINICAL TESTING

Precision

Three samples representing low, medium and high cell levels of CD3+ and CD4+ were used for these studies. Each sample was run 21 times to collect intra-assay precision data. The range of CVs for CD3+ cells, observed for all samples, was 4.9% (count of 3602 cells/µL) to 6.2% (count of 549 cells/µL). The range of CVs for CD4+ cells, observed for all samples, was 4.7% (count of 1996 cells/µL) to 6.9% (count of 369 cells/µL).

Dilution Recovery

Recovery was within +/_ 10% of expected value for levels tested from 0 to 1693 cells/µL for CD3+CD4+ cells and 0 to 3923 cells/µL for CD3+ cells.

Method Comparison

We have selected a 70 samples for this study representing a wide range of results. For CD3+ the range is 1 cell / µL to 2463 cells / µL. For CD4+ the range is 0 cells / µL to 1947 cells / µL. There is strong correlation between Thermo Scientific Cyto-Cal™ Count Tubes and the predicate BD Trucount Tubes in all of these ranges. The correlation coefficient (R value) for both CD3+ and CD4+ to reference method is > than 0.99.

Carryover Study

Carry-over from a high cell count sample to a low cell count sample is less than 5%.

Sample Stability

Cells count are within +/-10% of first test for up to 72 hours at 2 to 8 °C for blood samples, and for up to 12 hours at 2 to 8 °C for antibody labeled and lysed blood samples.

Reagent Shelf-Life Stabilities

Real time stability studies demonstrate the reagent is stable for at least 16 months at room temperature. Stability studies will continue for 24 months.

External Evaluation

The external site studies included a wide panel for fluorescent labeled monoclonal antibody (CD3, CD4, CD8, CD16, CD19, and CD56). The commonly used cell types including CD3+, CD4+, CD8+, CD16+CD56+, CD19+, and CD4/CD8 ratio are tabulated and compared to the reference BD Trucount method and Thermo Scientific Cyto-Cal™ Count Tubes method. All of the method comparison results show a strong correlation between Thermo Scientific Cyto-Cal™ Count Tubes and the predicate BD Trucount Tubes in all of these cell types. The correlation coefficients (r-value) meet the acceptance criteria.

CONCLUSION

As summarized, the Thermo Scientific Cyto-Cal™ Count Tubes are substantially equivalent to the BD Trucount Tubes. Substantial equivalence has been demonstrated through performance testing to verify that the device functions as intended and that design specifications have been satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 18 2009

Microgenics Corporation
Thermo Fisher Scientific, Clinical Division
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Re: k090810
Trade/Device Name: Thermo Scientific Cyto-Cal™ Count Tubes
Regulation Number: 21 CFR 864.5220
Regulation Name: Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: September 2, 2009
Received: September 4, 2009

Dear Ms. Charter:

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

Maria M. Chan, PhD
Director
Division of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K090810

Device Name: Thermo Scientific Cyto-Cal™ Count Tubes

Indication For Use:

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This in vitro diagnostic device is intended for clinical use only.

Prescription Use ___X___ And/Or Over the Counter Use

(21 CFR Part 801 Subpart D) (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)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K090810