

K103302

### 510(k) Summary

Life Technologies Corporation - StemPro® MSC SFM Medium

FEB 18 2011

**Device Name:** StemPro® MSC SFM Medium

**Common/Usual Name:** StemPro® MSC SFM

**Classification Name:** Tissue culture media for human *ex vivo* tissue and cell culture processing applications (per 21 CFR § 876.5885)

**Product Code:** NDS

**Submitter:** Life Technologies Corporation  
3175 Staley Road  
Grand Island, New York 14072

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**Facsimile:** (716) 774-0230

**Email:** kelli.tanzella@lifetech.com

**Contact:** Kelli Tanzella, Ph.D.

**Date Prepared:** October 11, 2010

**Predicate Device:**

<u>Trade Name</u>	<u>Manufacturer</u>	<u>510(k)</u>
Knockout™ SR Medium	Life Technologies Corporation	K100616

**Intended Use**

StemPro® MSC SFM Medium is a liquid tissue culture media product intended for human *ex vivo* tissue and cell culture processing applications.

**Substantial Equivalence**

The tissue culture media presented in this 510(k) submission, StemPro® MSC SFM Medium is substantially equivalent to Knockout™ SR Medium 510(k) K100616 manufactured by Life Technologies Corporation. Knockout™ SR Medium received 510(k) clearance from the FDA on May 20, 2010 as a Class II Device, and is listed under Product Code 78 NDS (Tissue culture media for human *ex vivo* tissue and cell culture processing applications). The 510(k) for Knockout™ SR Medium was reviewed by the gastroenterology control panel.

A. These tissue culture products (StemPro® MSC SFM and Knockout™ SR Medium) are used for human *ex vivo* tissue and cell culture processing applications and have the same principles of operation, technological characteristics, efficacy (generic cellular growth and maintenance) and safety (consistency in chemical content and formulation, biocompatibility with cells, and purity).

**Intended Uses**

StemPro® MSC SFM Medium is a tissue culture product intended for human *ex vivo* tissue and cell culture processing applications. This device is a chemically defined tissue culture media used to support the growth or maintenance of human tissue or cells in culture.

**B. Principles of Operation and Technological Characteristics**

StemPro® MSC SFM is a serum-free medium (SFM) specially formulated for the growth and expansion of human mesenchymal stem cells (MSCs). StemPro® MSC SFM enables human MSC growth and increased consistency compared to classical serum-supplemented medium. In addition, human MSCs can be expanded for multiple passages while maintaining their multipotential phenotype (i.e. ability to differentiate into osteogenic, chondrogenic, adipogenic lineages). StemPro® MSC SFM contains two components: StemPro® MSC SFM Basal Medium and StemPro® MSC SFM Supplement.

**C. Pre-Clinical Testing**

Performance standards under Section 514 of the Federal Food, Drug, and Cosmetic Act have been established in Guidance Document “Class II Special Controls Guidance Document: Tissue Culture Media for Human *Ex Vivo* Tissue and Cell Culture Processing Applications; Final Guidance for Industry and FDA Reviewers,” issued May 16, 2001. The specific assay tests and Life Technologies Corporation’s equivalent tests are described below in greater detail.

Special Control Objective	Life Technologies Corporation Knockout™ SR Medium
Demonstrate lack of potential toxicity of materials in the media to cells or tissue and demonstrate support of tissue and cell growth	StemPro® MSC SFM Performance Assay
Demonstrate lack of endotoxin or pyrogen contamination	Limulus Ameobocyte (LAL) test (25 USP Monograph <85>)
Validation of Aseptic Processing and Sterility Assurance Level (SAL)	Determination of SAL to be $\geq 10^{-3}$ compliance with GMP requirements

	regarding aseptic processing
Demonstrate Chemical purity	Incoming Raw Material testing using USP, ACS, FCC, GIBCO, or Cell Culture requirements

**Stability/Shelf-Life**

Life Technologies Corporation performs shelf life testing for StemPro® MSC SFM Medium using retained product stored at 2° - 8° C. In addition, a minimum of one new production lot of StemPro® MSC SFM Medium is tested each year to verify that the product continues to meet the established shelf life. Based on analysis of product performance over time, Life Technologies Corporation has established a shelf life of twelve months for the StemPro® MSC SFM Medium formulation. Stability testing involves the assessment of these functional aspects of media, including demonstrating: (1) that the pH continues to meet specifications; and (2) the media is not cytotoxic and supports the growth of mammalian cells. The pH is tested to demonstrate that the media is not chemically altered during its storage. In assessing cytotoxicity, Life Technologies Corporation demonstrates that the media functions in supporting the growth of mammalian cells and that the media does not become toxic to mammalian cells during storage.

In addition, results from the studies indicate the container/closure system provides protection from microbial contamination.

**D. Conclusion**

StemPro® MSC SFM and Knockout™ SR Medium are used for human *ex vivo* tissue and cell culture processing applications and have the same principles of operation, technological characteristics, efficacy (generic cellular growth and maintenance) and safety (consistency in chemical content and formulation, biocompatibility with cells, and purity). Their efficacy in supporting the survival, growth, development, and maintenance of human cells or tissue culture systems has been well established in scientific publications included in this submission. StemPro® MSC SFM and Knockout™ SR Medium are manufacturer in accordance with QSR requirements and are labeled as aseptically processed. Thus, StemPro® MSC SFM is substantially equivalent to the legally marketed device intended for the human *ex vivo* tissue and cell culture processing applications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Kelli L. Tanzella, Ph.D.  
Sr. Manager, Americas Regulatory Affairs  
Life Technologies™ Inc.  
3175 Staley Road  
GRAND ISLAND NY 14072

FEB 18 2011

Re: K103302  
Trade/Device Name: StemPro® MSC SFM Medium – StemPro® MSC SFM Basal  
Medium and StemPro® MSC SFM Supplement for *ex-vivo*  
Tissue and Cell Culture  
Regulation Number: 21 CFR §876.5885  
Regulation Name: Tissue culture media for human *ex vivo* tissue and cell culture  
processing applications.  
Regulatory Class: II  
Product Code: NDS  
Dated: February 17, 2011  
Received: February 18, 2011

Dear Dr. Tanzella:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related

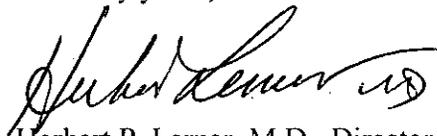
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adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)  
Division of Reproductive, Gastro-Renal  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K103302

Device Name: StemPro® MSC SFM Medium

**Indications for Use:**

StemPro® MSC SFM Medium is a liquid tissue culture medium products intended for human *ex vivo* tissue and cell culture processing applications.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHRE PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Gastro-Renal, and  
Urological Devices  
510(k) Number K103302