



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

ThermoGenesis Corporation  
c/o John R. chapman, Ph.D.  
VP, Scientific Affairs and R&D]  
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Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center-WO66-G609  
Silver Spring, MD 20993-0002

MAR 29 2010

Ré: k081345

Trade/Device Name: AXP Platform MarrowXpress™ System Model 8-5137, 8-5138  
and 8-5139

Regulation Number: 21 CFR 862-2050

Regulation Name: General purpose laboratory equipment labeled or promoted for a  
specific medical use

Regulatory Class: Class I Exempt

Product Code: JQC

Dated: May 12, 2008

Received: May 14, 2008

Dear Dr. Chapman:

This letter corrects our substantially equivalent letter of July 10, 2008.

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 (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.

The Office of In Vitro Diagnostic Device Evaluation and Safety has determined that there is reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 510(i)(1)(E) of the Act, the following limitation must appear in the Warnings and Precautions section of the devices labeling:

The safety and effectiveness of this device for in vivo indications for use has not been established.

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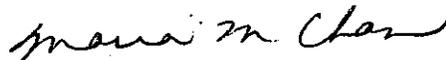
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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,



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

**Indications For Use**

510(k) Number (If known): K081345

Device Name: AXP Platform MarrowXpress™ System

Indications For Use:

The AXP Platform MarrowXpress System is intended to be used in the clinical laboratory or intraoperatively at the point of care for preparation of a cell concentrate from bone marrow.

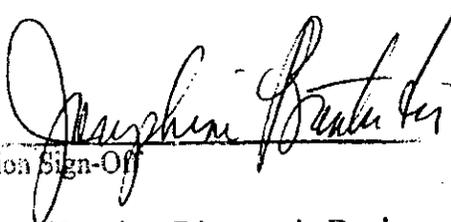
Prescription Use  X   
(Per 21 CFR 801 Subpart D)

OR

Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 807 Subpart C)

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

K081345

**510(k) Summary**

**SUBMITTER:** ThermoGenesis Corporation  
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**CONTACT PERSON:** John Chapman, PhD  
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**DATE PREPARED:** May 12, 2008

**DEVICE TRADE NAME:** AXP Platform MarrowXpress System

**COMMON/USUAL NAME:** General Purpose Laboratory Equipment for Clinical Use

**CLASSIFICATION NAME:** General Purpose Laboratory Equipment Labeled or Promoted for a Specific Medical Use (21 CFR 862.2050)

**PREDICATE DEVICE:** Harvest Technologies SmartPReP2 System (K052925)

**DEVICE DESCRIPTION:**

The AXP Platform MarrowXpress System is a semi-automated, closed system that harvests a precise, operator-determined volume of stem cell-rich buffy coat from human bone marrow. The system consists of the following major components 1) disposable Processing Bag Set, 2) rechargeable NiMH battery-powered MXP Device, 3) AC-powered Docking Station, and 4) XpressTRAK software. Accessories include a bar code scanner, weight kit, counterweight, and MXP Device stand. The AXP Platform MarrowXpress System is intended to be used in the clinical laboratory or intraoperatively at the point of care for preparation of a cell concentrate from bone marrow.

The MXP Device separates the bone marrow aspirate into red blood cells, plasma, and buffy coat utilizing a standard laboratory centrifuge, and meters each of these components into a separate compartment within the disposable Processing Bag Set. The Processing Set is provided sterile with a non-pyrogenic fluid pathway, and is for single use only.

After processing, the MXP Device is placed into the AC powered Docking Station. The Docking Station automatically downloads processing data into the XpressTRAK software and recharges the MXP Device battery pack. The following information is communicated to the XpressTRAK software via a serial connection: MXP Device serial number, errors detected during processing, duration of processing, g force during processing, and mass calculation data.

The XpressTRAK application software manages and stores the bone marrow processing data, verifies operational status of the system, and has report production capabilities. The software permits the user to search and sort collected data using the following fields: centrifuge ID, bone marrow aspirate unit number, Processing Bag Set lot number, buffy coat volume, user-definable fields, user name, or date and time.

**STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON**

A comparison of device features and in-vitro test data (TNC, MNC, platelet and stem cell recovery, cell viability and concentrate hematocrit) demonstrate that the AXP Platform MarrowXpress System is substantially equivalent to the currently marketed Harvest Technologies SmartPReP2 Centrifuge System.