K071934

510(k) Summary

OCT 1 1 2007

Manufacturer:	Biomet Manufacturing Corp. P.O. Box 587 56 East Bell Drive Warsaw, Indiana 46581
Submitted By:	Biomet Biologics, Inc. P.O. Box 587 56 East Bell Drive Warsaw, Indiana 46581
Proprietary Name:	MarrowStim™ Concentration Kit and MarrowStim™ Mini Concentration Kit
Classification name:	General purpose laboratory equipment labeled or promoted for a specific medical use (21 CFR 862.2050)
Common/Usual Name:	Centrifuge for Clinical Use
Product Code:	JQC, FGF, KSS
Substantial Equivalence:	Documentation is provided which demonstrated the MarrowStim™ Concentration Kit and MarrowStim™ Mini Concentration Kit to be substantially equivalent to other legally marketed devices.
Device Description:	The MarrowStim™ Concentration Kit and MarrowStim™ Mini Concentration Kit consist of a table-top, swinging bucket centrifuge and accessories to allow for preparation of platelet poor plasma and platelet concentrate from blood, and for preparation of a cell concentrate from bone marrow. The MarrowStim™ and MarrowStim™ Mini Concentration Kits have the same indications for use for which the Harvest SmartPReP2 Centrifuge System (K052925) was cleared.
Intended Use:	The MarrowStim™ Concentration Kit and the MarrowStim™ Mini Concentration Kit are intended to be used in the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of platelet poor plasma and platelet concentrate from a small sample of blood and for preparation of a cell concentrate from bone marrow.
Material:	Polymeric Medical Grade Plastics

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 11 2007

Mary L. Verstynen
Biomet Manufacturing Corp.
56 East Bell Drive
Warsaw, Indiana 46582

Re: k071934
Trade/Device Name: MarrowStim ™ Concentration Kit and MarrowStim ™ Mini Concentration Kit
Regulation Number: 21 CFR 862.2050
Regulation Name: Centrifuge for Clinical Use
Regulatory Class: Class I
Product Code: JQC
Dated: July 5, 2007
Received: July 19, 2007

Dear Ms. Verstynen:

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.

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 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings and Precautions section of the device's labeling:

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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); 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 Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K071934

Device Name: MarrowStim™ Concentration Kit and MarrowStim™ Mini Concentration Kit

Indications For Use:

The MarrowStim™ Concentration Kit and the MarrowStim™ Mini Concentration Kit are intended to be used in the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of platelet poor plasma and platelet concentrate from a small sample of blood and for preparation of a cell concentrate from bone marrow.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

Josephine Bautista

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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