DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

November 7, 2012

Cytomedix, Incorporated
Attention: Nathan A. Beaver
Regulatory Counsel
Foley & Lardner LLP
300 K Street, NW, Suite 600
Washington, DC 20007

Re: BK110046
Trade/Device Name: Angel® Concentrated Platelet Rich Plasma (cPRP) System
Regulation Number: 21 CFR 864.9245
Regulation Name: Automated blood cell separator
Regulatory Class: II
Product Code: ORG
Dated: October 26, 2012
Received: November 1, 2012

Dear Mr. Beaver:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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 Cellular, Tissue, and Gene Therapies has determined that there is a 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 device's labeling:

1. The device must be labeled as follows:

   "Platelet Rich Plasma prepared from a mixture of whole blood and bone marrow may contain higher levels of plasma free hemoglobin than Platelet Rich Plasma prepared from whole blood."

This labeling must follow the regulations for prominence of required label statements as set forth in Title 21 CFR 801.15, including placement in the instructions for use.

2. All labeling and promotional material will refer to the output of the device as Platelet Rich Plasma or "PRP"; if the output of the device is referred to as anything but Platelet Rich Plasma or "PRP", it will be considered misbranded under Title 21 CFR 801.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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,

Celia M. Witten, Ph.D., M.D.
Director
Office of Cellular, Tissue, and Gene Therapies
Center for Biologics Evaluation and Research

Enclosure

Indications for Use (CBER/OCTGT)

510(k) Number (if known): BK110046

Device Name: Angel® Concentrated Platelet Rich Plasma (cPRP) System

Indications for Use: To be used in the clinical laboratory or intraoperatively at the point of care for the safe and rapid preparation of platelet poor plasma and platelet concentrate (platelet rich plasma) from a small sample of whole blood or a small mixture of blood and bone marrow. The platelet rich plasma can be mixed with autograft and/or allograft bone prior to application to an orthopedic site.

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 CBER, Office of Cellular, Tissue and Gene Therapies

APPROVED

Office Sign-Off
Office of Cellular, Tissue and Gene Therapies

510(k): BK110046