January 2, 2018

Alliance Partners, LLC
Attention: Kristiina Gilkey
Quality Assurance and Regulatory Affairs Manager
14206 Northbrook Drive
San Antonio, TX 78232

Re: BK170108
Trade/Device Name: Cyclone Concentrating System
Regulation Number: 21 CFR 864.9245
Regulation Name: Automated blood cell separator
Common Name: Platelet and plasma separator for bone graft handling
Regulatory Class: Class II
Product Code: ORG
Dated: December 1, 2017
Received: December 4, 2017

Dear Ms. Gilkey:

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

The Office of Tissues and Advanced 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 limitations apply to the device's labeling:

1. The device must be labeled as follows:

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

This labeling must follow the regulations for prominence of required label statements as set forth in 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 to be misbranded under 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Wilson W. Bryan, M.D.
Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Enclosure

Indications for Use (CBER/OTAT)

510(k) Number: BK170108

Device Name: Cyclone Concentrating System

Indications for Use:

The Cyclone Concentrating System is designed to be used intraoperatively at the point of care for the safe and rapid preparation of a platelet concentrate (platelet rich plasma or PRP) from a small sample of a mixture of peripheral blood and bone marrow. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improved handling characteristics.

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

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

Concurrence of CBER, Office of Tissues and Advanced Therapies

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Office Sign-Off
Office of Tissues and Advanced Therapies
510(k): BK170108