510(k) SUBSTANTIALLY EQUIVALENT
May 10, 2018

Arthrex, Inc.
Attention: Laura Medlin
1370 Creekside Boulevard
Naples, FL 34108-1945

Re: BK170144
Trade/Device Name: Thrombinator System for use with the Arthrex Angel concentrated Platelet Rich Plasma (PRP) 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: April 11, 2018
Received: April 12, 2018

Dear Ms. Medlin:

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.

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 Bryan -S

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Date 2018.05.10 14 34 41 -04'00'

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

Enclosure
Indications for Use

Indications for Use (CBER/OTAT)

510(k) Number: BK170144

Device Name: Thrombinator System for use with the Arthrex Angel concentrated Platelet Rich Plasma (PRP) System

Indications for Use:

The Arthrex Angel concentrated Platelet Rich Plasma (cPRP) System is designed 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.

The Thrombinator System for use with the Arthrex Angel concentrated Platelet Rich Plasma (cPRP) System is designed for the preparation of autologous serum from anticoagulated peripheral blood or platelet poor plasma that is to be mixed with PRP and autograft or allograft bone prior to application to a bony defect for improving 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 ANOTHER PAGE IF NEEDED)

Concurrence of CBER, Office of Tissues and Advanced Therapies

APPROVED
By Wilson W. Bryan at 1:26 pm, May 10, 2018

Office Sign-Off
Office of Tissues and Advanced Therapies

510(k): BK170144