



Substantially Equivalent

April 24, 2024

Arthrex, Inc.
Attention: Emmarie Halteman
Senior Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, FL 34108

Re: BK241060/0

Trade/Device Name: Arthrex Thrombinator 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: March 22, 2024
Received: March 25, 2024

Dear Emmarie Halteman:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laura Ricles, PhD
Director
Division of Cell Therapy 2
Office of Cellular Therapy and Human Tissue
Office of Therapeutic Products
Center for Biologics Evaluation and Research

Enclosure

Indications for Use (CBER/OTP)

510(k) Number : BK241060/0

Device Name: Arthrex Thrombinator System

Indications for Use:

The Thrombinator System for use with Arthrex PRP Systems (Arthrex Angel concentrated Platelet Rich Plasma cPRP System or Arthrex Double Syringe (ACP) System or Arthrex ACP Max™ Platelet-Rich Plasma (PRP) System) is designed for the preparation of autologous serum from anticoagulated or non-anticoagulated peripheral blood, platelet poor plasma, or platelet rich plasma (PRP) 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 ON ANOTHER PAGE IF NEEDED)

Concurrence of CBER, Office of Therapeutic Products

Office Sign-Off
Office of Therapeutic Products

510(k): BK241060/0