November 19, 2021

Arthrex Inc.
Mr. Nick Moore, MBA
Principal, Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K213213
Trade/Device Name: Arthrex Vortex Threaded Bone Marrow Recovery Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: September 27, 2021
Received: September 29, 2021

Dear Mr. Moore:

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. 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 located 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: CDRH 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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213213

Device Name
Arthrex Vortex™ Threaded Bone Marrow Recovery Needle

Indications for Use *(Describe)*
The Arthrex Vortex™ Threaded Bone Marrow Recovery Needle is intended for use in aspirating bone marrow.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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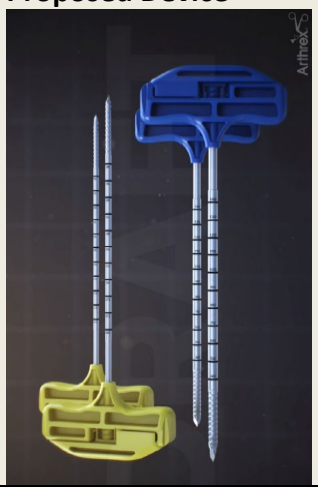
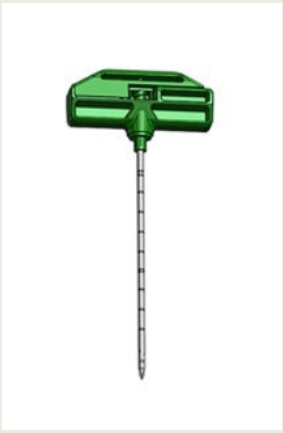
510(k) Summary

Date Prepared	November 18, 2021
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Mr. Nick Moore, MBA Principal, Regulatory Affairs 1-239-643-5553, ext. 71883 nick.moore@arthrex.com
Name of Device	Arthrex Vortex™ Threaded Bone Marrow Recovery Needle
Common Name	Gastroenterology-urology biopsy instrument
Product Code	KNW
Classification Name	21 CFR 876.1075 Gastroenterology-urology biopsy instrument
Regulatory Class	II
Predicate Devices	K131157 Ranfac Bone Marrow Aspiration Needle
Reference Device	K150563 Ranfac Marrow Cellution Bone Marrow Aspiration Needle K062365: Arthrex Bone Marrow Aspirate Kit
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Vortex™ Threaded Bone Marrow Recovery Needle.
Device Description	The Arthrex Vortex™ Threaded Bone Marrow Recovery Needle is a single-use aspiration needle comprised of a 304 stainless steel (SS) cannula with a molded plastic Acrylonitrile Butadiene Styrene (ABS) handle, and a 304 stainless steel stylet with a molded plastic (ABS) handle which mates with the cannula handle when the stylet is inserted through the cannula. The distal end of the cannula is threaded and has vent holes for bone marrow aspirate recovery. The needle will be offered in 8G and 13G sizes. It will also be offered in an open tip configuration as well as a closed tip configuration. The Arthrex Vortex™ Threaded Bone Marrow Recovery Needle can be hammered or twisted into the bone to access the marrow. A standard syringe (not included) will be attached to the Luer-lock portion of the ABS handle and negative pressure is applied to withdraw the bone marrow aspirate. The device can be used anywhere bone marrow aspirate can be collected such as the iliac crest, vertebral bodies, femur, humerus and/ or the calcaneus. The threaded the portion on the distal end of the cannula will allow for precise depth control of the device while performing the aspiration.

Indications for Use	The Arthrex Vortex™ Threaded Bone Marrow Recovery Needle is intended for use in aspirating bone marrow.
Technology Comparison	The Arthrex Vortex™ Threaded Bone Marrow Recovery Needle has the same technological characteristics and design as the predicate device cleared in K131157 except for the following differences: threaded distal end, gauge diameter and sterilization method. Side by side comparison of the proposed device and the predicate device provided below:

Item	**Proposed Device** 	**Predicate Device K131157** 	**Equivalence**
Indications for use	The Arthrex Vortex™ Threaded Bone Marrow Recovery Needle is intended for use in aspirating bone marrow.	The Ranfac Bone Marrow Aspiration Needle is intended for use in aspirating bone marrow	
Regulation Number	876.1075	876.1075	Identical
Regulation name	Gastroenterology-urology biopsy instrument	Gastroenterology-urology biopsy instrument	Identical
Regulatory Class	Class II	Class II	Identical
Product Code	KNW	KNW	Identical
Classification Panel	Gastroenterology/Urology	Gastroenterology/Urology	Identical
Material	304 SS/ ABS	304 SS/ ABS	Identical
Sizes	8G and 13G	8G and 11G	Proposed device: 8G and 13G

			Predicate device: 8G and 11G Minor difference in geometry.
Performance characteristics	Needle bores into bone to access marrow cavity	Needle bores into bone to access marrow cavity	Identical
Sterilization method	Gamma Irradiation	Ethylene Oxide Gas	Proposed device: Gamma Predicate Device: EO
SAL	10^{-6}	10^{-6}	Identical
Shelf Life	5 years	5 years	Identical
Single Use	Yes	Yes	Identical
Performance testing results	Needle clog testing: No visible signs of leakage or disassembly Hammer insertion testing: No signs of deformation or prevention of aspiration	Needle clog testing: No visible signs of leakage or disassembly Hammer insertion testing: No signs of deformation or prevention of aspiration	Identical

Performance Data

Arthrex completed testing on the proposed device and predicate (K131157) to demonstrate the performance. Insertion and removal torque, fatigue, failure torque and hammer insertion were tested on the proposed device. Testing for leakage and clogging as well as hammer insertion was performed on the predicate device (K131157). Failure torque testing was also performed on predicate device for characterization only. No instances of leakage/clogging were observed when aspirating the test solution for the proposed device or for the predicate. No failures were observed during hammer insertion testing for the proposed device or for the predicate. Additionally, after hammer insertion testing, both the proposed device and predicate device showed no signs of mechanical deformation or prevention of aspiration capabilities.

Material Mediated Pyrogenicity was performed on a comparable device. Based on the results of the study the test article showed no evidence of material mediated pyrogenicity. In addition, bacterial endotoxin testing is conducted in accordance with AAMI ST72 2019 and meets the 20EU/device for routine monitoring of sterile products.

	Cytotoxicity, Sensitization, Irritation, Genotoxicity, Systemic Toxicity, Implantation, and Material Characterization testing was conducted on the Arthrex Vortex™ Threaded Bone Marrow Recovery Needle in accordance with ISO 10993-1:2018.
Conclusion	The Arthrex Vortex™ Threaded Bone Marrow Recovery Needle is substantially equivalent to the predicate device in which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate device are considered minor and do not raise different questions concerning safety or effectiveness. The submitted mechanical testing data demonstrates that the proposed device is substantially equivalent to that of the predicate device for the desired indications. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the proposed device is substantially equivalent to the currently marketed predicate device.