Arthrex Inc.
Rebecca Homan
Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K201677
Trade/Device Name: Arthrex Mesh Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC, HTY
Dated: June 15, 2020
Received: June 19, 2020

Dear Rebecca Homan:

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,

On behalf of Shumaya Ali, M.P.H
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201677

Device Name

Arthrex Mesh Plates

Indications for Use *(Describe)*

The Arthrex Mesh Plates are intended for use in stabilization of fresh fractures, revision procedures, osteotomies, joint fusion and reconstruction of small bones and bone fragments of the hand/wrist, foot/ankle, osteopenic bone and patella fractures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared	September 1, 2020
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Rebecca R. Homan Regulatory Affairs Specialist 1-239-643-5553, ext. 73429 rebecca.homan@arthrex.com
Name of Device	Arthrex Mesh Plates
Common Name	Plate, fixation, bone
Product Code	HRS, HWC
Classification Name	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class	II
Predicate Device	K170547: Arthrex Mesh Plate System (Primary Predicate) K143702: Arthrex Blunt Tip Screws with FiberTape (Secondary Predicate)
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for patella fracture indications for the Arthrex Mesh Plates.
Device Description	The Arthrex Mesh Plates are manufactured from either titanium alloy or stainless steel. The plates are 1.3 mm thick in a semi-contoured, mesh-like design. The plates are available in long and short versions ranging from 50 mm to 115 mm in length. The plates are designed for the surgeon to cut to a desired length as needed. The Arthrex Mesh Plates are intended to be used with existing FDA cleared Arthrex screws. The Arthrex Mesh Plates are sold sterile and non-sterile and are single use.
Indications for Use	The Arthrex Mesh Plates are intended for use in stabilization of fresh fractures, revision procedures, osteotomies, joint fusion and reconstruction of small bones and bone fragments of the hand/wrist, foot/ankle, osteopenic bone and patella fractures.
Performance Data	Tensile and cyclic testing was conducted to demonstrate that the Arthrex Mesh Plates perform statistically equivalent to the predicate device cleared under K143702. MRI force, torque, and image artifact testing were conducted in accordance with FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, ASTM F2052 *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*, ASTM F2119 *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*, ASTM F2182 *Standard Test Method for Measurement of Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging* and ASTM F2213 *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*. Bacterial Endotoxins Test (BET) was performed on the Arthrex Mesh Plates utilizing the Kinetic Chromogenic Method in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14. The testing conducted demonstrates that the Arthrex Mesh Plates meet pyrogen limit specifications.

	Cytotoxicity, Sensitization, Irritation, Genotoxicity, Systemic Toxicity, Subchronic/Subacute Toxicity, Implantation and Material Characterization testing was conducted on the Arthrex Mesh Plates in accordance with ISO 10993-1:2018. Assessment of physical product attributes including product design, size, and materials as well as the conditions of manufacture and packaging has determined that the Arthrex Mesh Plates do not introduce additional risks or concerns regarding sterilization and shelf-life.
Technological Comparison	The Arthrex Mesh Plates are substantially equivalent to the predicate devices cleared under K170547 and K143702 in which the basic design features, intended use, fundamental scientific technology, materials, sterility, packaging and shelf-life are identical. The Arthrex Mesh Plates are used with existing FDA cleared Arthrex screws (K143614, K150456 and K170547) with the optional use of the Arthrex Blunt Tip Screws (K143702) for patella fractures; whereas the predicate Arthrex Blunt Tip Screws with FiberTape (K143702) consists of standalone screws used in conjunction with FiberTape Suture for patella fractures. The Arthrex Mesh Plates were evaluated for MR Conditional labeling; whereas the predicate devices cleared under K170547 and K143702 were not evaluated for MR Conditional labeling. The Arthrex Mesh Plates are substantially equivalent to the predicate devices cleared under K170547 and K143702, with minor dimensional modifications with no change to intended use or function. Any differences between the Arthrex Mesh Plates and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.
Conclusion	The Arthrex Mesh Plates are 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 ultimate tensile strength, stiffness and cyclic fatigue of 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.