K121124

MAY 16 2012

3 510(k) Summary of Safety and Effectiveness

Date Summary Prepared	April 11, 2012
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Christina Flores Regulatory Affairs Specialist Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1819 Fax: 239/598.5508 Email: Christina.flores@arthrex.com
Trade Name	Arthrex Mixing and Delivery System
Common Name	Piston Syringe
Product Code -Classification Name ***CFR***	Syringe, Piston FMF 21 CFR 880.5860
Predicate Device	*K062986 Medtronic Graft Delivery Syringe* *K012738, DePuy Symphony Graft Delivery System* *K062365 Arthrex Aspirate Kit*
Purpose of Submission	This **Traditional 510(k)** premarket notification is submitted to obtain clearance for the *Arthrex Mixing and Delivery System.*
Device Description and Intended Use	The ***Arthrex Mixing and Delivery System*** consists of a piston syringe with a movable plunger and cap to facilitate mixing and delivery; straight and curved (tuohy) delivery needles; a mating obturator for delivery needles; luer connectors; and a funnel to facilitate filling of the syringe barrel. The system will be offered with either a 3mL or 14 mL syringe barrel and may be provided either empty or pre-filled with allograft, autograft, or synthetic bone graft materials. The ***Arthrex Mixing and Delivery System***, like the predicates, is intended to provide the surgeons with a means to mix and deliver graft material to an orthopedic surgical site.

	Arthrex Mixing and Delivery System is indicated for the delivery of allograft, autograft, or synthetic bone graft materials to all orthopedic surgical sites. In addition, it is designed to facilitate pre-mixing of allograft, autograft, or synthetic bone graft materials with I.V. fluids, blood, plasma, platelet rich plasma, bone marrow or other specific blood component(s) as deemed necessary by the clinical use requirements.
Substantial Equivalence Summary	The ***Arthrex Mixing and Delivery System*** is substantially equivalent to the predicate devices, in which the basic features and intended uses are the same. Any differences between the ***Arthrex Mixing and Delivery System*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness. Based on the biocompatibility and mechanical testing performed, Arthrex, Inc. has determined that the ***Arthrex Mixing and Delivery System*** is substantially equivalent to the marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Arthrex, Incorporated
% Ms. Christina Flores
Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108

MAY 16 2012

Re: K121124
Trade/Device Name: Arthrex Mixing and Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: FMF
Dated: May 7, 2012
Received: May 8, 2012

Dear Ms. Flores:

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. 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2 Indications for Use Form

510(k) Number:_____

Device Name: **Arthrex Mixing and Delivery System**

The ***Arthrex Mixing and Delivery System*** is indicated for the delivery of allograft, autograft, or synthetic bone graft materials to all orthopedic surgical sites. In addition, it is designed to facilitate pre-mixing of allograft, autograft, or synthetic bone graft materials with I.V. fluids, blood, plasma, platelet rich plasma, bone marrow or other specific blood component(s) as deemed necessary by the clinical use requirements.

Prescription Use _X_ AND/OR Over-The-Counter Use _____

(Per 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 CDRH, Office of Device Evaluation (ODE)

1 of 1

Neil R. Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121124