# 510(k) Summary



K141245

JUL 09 2014

**Device Trade Name:** ETEX Mixing and Delivery System

**Manufacturer:** ETEX Corporation
675 Massachusetts Ave, 12th Floor
Cambridge, MA 02139

**Contact:** Andy Soman
Regulatory Affairs
Phone: 617-871-6342
Fax: 617-577-7170

**Date Prepared:** July 7, 2014

**Common Name:** Piston Syringe

**Classification:** 21 CFR 880.5860

**Class:** II

**Product Code:** FMF

**Indications For Use:**

The ETEX Mixing and Delivery System is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.

**Device Description:**

The ETEX Mixing and Delivery System is comprised of a commercially available disposable medical piston syringe (syringe barrel with female luer, plunger). The ETEX Mixing and Delivery System is provided sterile, for single use only.

**Predicate Device:**

The ETEX Mixing and Delivery System has the same indications for use, design, function, materials, and is substantially equivalent to the Zimmer Knee Creations Inc. Mixing Syringe System (K133021) and the Arthrex Mixing and Delivery System (K121124)

**Performance Standards:**

All necessary testing has been performed for the ETEX Mixing and Delivery System to assure substantial equivalence to the predicate device and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices.

The device design was qualified through the following tests:

- Simulated Use Testing
- Volume Verification
- Separation Force Testing
- Liquid Leak Testing
- Biocompatibility Evaluation

**Conclusion:**

The ETEX Mixing and Delivery System met all specified criteria and did not raise new safety or effectiveness questions. The indications, intended use, and fundamental scientific technology of the ETEX Mixing and Delivery System are the same as those for the predicate devices. Therefore, the ETEX Mixing and Delivery System is substantially equivalent to the Zimmer Knee Creations Inc. Mixing Syringe System (K133021) and the Arthrex Mixing & Delivery System (K121124).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 9, 2014

ETEX Corporation
Mr. Andy Soman
Regulatory Affairs
675 Massachusetts Avenue, 12th Floor
Cambridge, Massachusetts 02139

Re: K141245
Trade/Device Name: ETEX Mixing and Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: May 12, 2014
Received: May 14, 2014

Dear Mr. Soman:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# 1. Indications for Use

510(k) Number (if known): K141245

Device Name: ETEX Mixing and Delivery System

The ETEX Mixing and Delivery System is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S