K021071

JUL 1 2002

510(k) Notification

A. ADMINISTRATIVE INFORMATION

Applicant or Sponsor: Biomet, Inc.
P.O. Box 587
56 East Bell Drive
Warsaw, Indiana 46582
(FDA registration no. 1825034)

Contact Person: Lonnie Witham
Phone: (219) 267-6639
FAX: (219) 372-1683

Marketer/Distributor: Osseous Technologies, Inc., a Division of Biomet Orthopedics, Inc.
P.O. Box 587
56 East Bell Drive
Warsaw, IN 46582

Manufacturing Site(s):
Contract Manufacturer:
MicroMed, Inc.
124 Heritage Avenue
Portsmouth, NH 03801 (FDA registration no. 1220894)
Specification holder:
Implant Innovations, Inc., a Biomet Company
4555 Riverside Drive
Palm Beach Gardens, FL 33410 (FDA registration no. 1038806)

B. DEVICE IDENTIFICATION

Proprietary Name: Graft Delivery System

Common or Usual Name: Piston Syringe

Classification Name: Piston Syringe

Device Classification: 21 CFR 880.5860 Piston Syringe – Class II

Device Product Code: FMF

Performance Standards/Guidance Documents: No performance standards have been developed for this type of device.

Previous FDA Status: Per 21 CFR 880.5860 the device is Class II and may be cleared for marketing with a pre-market notification under section 510(k).

C. DEVICE DESCRIPTIVE INFORMATION

Intended Use: This device is intended for use in the delivery of allograft and autograft bone materials to an orthopedic surgical site. In addition, it is designed to facilitate pre-mixing of bone graft materials with I.V. fluids, blood, plasma, platelet rich plasma, bone marrow or other specific blood components as deemed necessary by the clinical use requirements.

Device Description: The Graft Delivery System will be configured using the following components. See **Exhibit 1 for drawings and supplier catalog Information.**

- Two commercially available disposable medical piston syringes
- Applicator tips

This Graft Delivery System will be sold in conjunction with CelSep® Centrifuge System (K994148). CelSep® Centrifuge System (K994148) that consists of a compact bench top centrifuge designed for multi-purpose use in medical, industrial, and scientific laboratories. that includes a single-use processing disposable.

Materials: Materials for the Graft Delivery System meet the requirements set forth in the current U.S. Pharmacopeia for Class IV and Class VI as well as the FDA modified ISO 10993-1 tests for biocompatibility for human body fluid of 30 days or less. Components are manufactured from medical grade resins.

Labeling: Sample labels and labeling are included in **Exhibit 2.**

Sterility Information: The Graft Delivery System consists of a 60cc Becton Dickinson disposable sterile syringe and a 10cc Becton Dickinson disposable sterile syringe. The devices are procured packaged and sterile, and will retain the original individual sterile package and labeling as provided from the Becton Dickinson. These same sterile disposable syringes were previously cleared for use in the processing disposable kit for the CelSep® Centrifuge System (K994148). Becton Dickinson has several premarket notifications cleared for marketing of piston syringes including K930321, K95064, and K980580. The two individual sterile packages will then be organized into a convenience pack by placing them in a rigid blister tray with a sealed Tyvek® lid. The outer lid of the kit will bear an Osseous Technologies label.

Packaging Description: A description of the packaging is in **Exhibit 2.**

Substantial Equivalence: The Graft Delivery System is substantially equivalent to the DePuy/AcroMed Symphony Graft Delivery System (K003286), a J &J Company, the Harvest Technologies SmartJet Bone Grafting Liquid Applicator (K011032), and the MicroMedics FibriJet Aerosol Applicator (K012868). **See Exhibit 3 for predicate devices.**

Summary Comparison **Osseous Tech., Symphony, and MicroMedics Delivery Systems**			
Characteristic	**Osseous Technologies** (This submission)	**DePuy AcroMed** Symphony (K003286) **Harvest Tech.** SmartJet (K011032)	**Micromedics** FibriJet (K012868)
Intended Use	Delivery of allograft, autograft to orthopedic surgical site and facilitate pre-mixing of bone graft with I.V. fluids, bleed, plasma, platelet rich plasma, bone marrow or other specific blood components as deemed necessary by the clinical use requirements.	Same as Osseous Tech.	For simultaneous delivery of two non-homogenous liquids to the same area.
Components	Commercially marketed piston syringes and applicator tips in straight and spray configurations	Same as Osseous Tech.	Same as Osseous Tech.
Labeling Includes Commercially Available Centrifuge	CelSep® Centrifuge System K994148	SmartPrep Centrifuge System K991430	None Known
Sterility	Sold Sterile – Single use –Disposable	Same as Osseous Tech.	Same as Osseous Tech.
Principle of Operation	Fluids dispensed from the applicator tip by depressing the syringe plunger(s)	Same as Osseous Tech.	Same as Osseous Tech.

D. SUMMARY OF SAFETY AND EFFECTIVENESS

A summary of information pertaining to the safety and effectiveness of this type of device is contained in **Exhibit 4 for Summary of Safety and Effectiveness**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2002

Biomet, Inc
Lonnie Witham
P. O. Box 587
Warsaw, Indiana 46581 – 0578

Re: K021071
Trade Name: Graft Delivery System
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: March 25, 2002
Received: April 2, 2002

Dear Mr. Witham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K021071

Device Name: Graft Delivery System

Indications For Use: This device is intended for use in the delivery of allograft and autograft bone materials to an orthopedic surgical site. In addition, it is designed to facilitate pre-mixing of bone graft materials with I.V. fluids, blood, plasma, platelet rich plasma, bone marrow or other specific blood components as deemed necessary by the clinical use requirements.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021071