K091722

MAR 12 2010

510(k) Summary

Applicant/Sponsor: Biomet Biologics, LLC
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581
Phone: 800-348-9500
www.biomet.com

Contact Person: Lonnie Witham
Summary Preparation Date: March 11, 2010

Device Trade Name: CoAxial™ Applicator System
Common Name: Piston Syringe

Classification Name: Piston Syringe FMF (21 CFR 880.5860)

Legally Marketed Predicate Devices To Which Substantial Equivalence Is Claimed:

510(k) Number	Predicate Device	Manufacturer
K011032	SmartJet™ Bone Grafting Liquid Applicator	Harvest Technologies Corp. Plymouth, MA 02360
K020252	SmartJet™ Liquid Grafting Applicator	Harvest Technologies Corp. Plymouth, MA 02360
K883338	Surgical Sealant Applicator (FibriJet®)	Micromedics, Inc. St. Paul, MN 55107

Device Description:
The CoAxial™ Applicator System consists of the CoAxial™ Spray Kit and CoAxial™ Applicator Tips. Within the CoAxial™ Spray Kit is a sterile, single-use, syringe type device (CoAxial™ Applicator), connector and Spray Tip. The CoAxial™ Applicator is comprised of two separate chambers to facilitate pre-mixing of bone graft materials with blood or blood products.

Statement of Intended Use:
The CoAxial™ Applicator System is designed to facilitate pre-mixing of allograft, autograft, or synthetic bone graft materials for application to an orthopedic surgical site, with autologous blood, plasma, platelet-rich plasma, or other specific blood component(s) as deemed necessary by the clinical use requirements

In addition, the CoAxial™ Applicator System is intended for the application of autologous blood, plasma, platelet-rich plasma, or other specific blood component(s), as deemed necessary by the surgeon's determination of the clinical use requirements to facilitate the preparation of

soft tissue autograft or allograft material prior to the application of the graft material to a repair site.

Summary of Technological Characteristics:
The CoAxial™ Applicator is a dual-syringe system, similar to all three predicate devices. It is comprised of an inner, smaller syringe and an outer, larger syringe, instead of two separate syringes. While the design differs from the predicates, it is designed to function in the same manner. Two fluids can be held by separate syringes and all applicators allow for dispensing the two liquids simultaneously.

The dimensions of the two chambers that comprise the CoAxial™ Applicator are 12 ml (outer) and 1.2 ml (inner), which are similar to the 10 ml and 1 ml volumes held by the two syringes in both the Harvest SmartJet™ Bone Grafting Liquid Applicator predicates. The 10:1 ratio of dispelled fluids is the same for the SmartJet™ systems. The FibriJet® Applicator has a ratio of 11:1.

Summary of Performance Data:
Torque testing (separation force, unscrewing torque, ease of assembly, resistance of overriding, stress cracking) and volume accuracy testing was performed on the CoAxial™ Applicator. Results either met the acceptance criteria set forth within the applicable standard, or if there were no set acceptance criteria, the results were acceptable per the test protocol.

Assembly time and mixing thoroughness were evaluated against the FibriJet® Applicator, manufactured by Micromedics. The CoAxial™ Applicator System demonstrated ease of use advantage over the FibriJet® Applicator, with a three-fold decrease in assembly time using an assembly test subject who was unfamiliar with either device assembly. The results of the mixing analysis were comparable for the two devices.

The CoAxial™ Applicator System is intended to be used for the application of liquids in a 10:1 ratio, and the instructions for use clearly define how to achieve this application. Bone graft handling testing was performed to compare the effect that an 11:1, 10:1, and 9:1 ratio of PRP/PPP to autologous serum has on bone graft cohesive strength. No statistically significant differences between the groups were observed.

Non-Clinical Testing:
Non-clinical laboratory testing was performed to determine substantial equivalence. Testing indicated that the Fat Concentration System is substantially equivalent to currently marketed predicate devices. The results indicated that the device was functional within its intended use.

Clinical Testing:
None provided as a basis for substantial equivalence.

Adverse Events:
A search of FDA's MAUDE database for the period of Jan. 1, 2008 thru Jan. 31, 2010 revealed that no adverse events were reported under K011032, K020252, and K883338.

Substantial Equivalence:
The CoAxial™ Applicator System is shown to be substantially equivalent to the previously cleared devices, the Harvest SmartJet™ Bone Grafting Liquid Applicator- K011032, SmartJet™ Liquid Grafting Applicator - K020252, and the Micromedics FibriJet® Applicator - K883338. The design, sizes, and materials are similar to the aforementioned predicates and there are no new performance characteristics that introduce new safety and/or effectiveness issues.

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

Mr. Lonnie Witham
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Re: K091722
Trade/Device Name: CoAxial Applicator System
Regulation Number: 21CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: March 3, 2010
Received: March 4, 2010

Dear Mr. Witham:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): NA

Device Name: CoAxial Applicator System

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In addition, the CoAxial Applicator System is intended for the application of autologous blood, plasma, platelet-rich plasma, or other specific blood component(s), as deemed necessary by the surgeon's determination of the clinical use requirements to facilitate the preparation of soft tissue autograft or allograft material prior to the application of the graft material to a repair site.

Prescription Use YES AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CBER, Office of Blood Research and Review

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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