



Food and Drug Administration  
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August 27, 2014

Biomet Biologics LLC  
Mr. Lonnie Witham  
Scientific Affairs Project Manager - Biologics  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K141762

Trade/Device Name: PerFuse Percutaneous Decompression System  
Regulation Number: 21 CFR 880.5860  
Regulation Name: Piston, Syringe  
Regulatory Class: II  
Product Code: FMF  
Dated: June 30, 2014  
Received: July 01, 2014

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 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



**Preparation Date:**

May 30, 2014

**Applicant/Sponsor:**

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**Contact Person:**

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**Trade Name:** PerFuse Percutaneous Decompression System

**Common Name:** Graft Delivery Syringe and Decompression Instrument

**Classification name:** Piston Syringe (21 CFR 888.5860 Product Code: FMF)

**Regulatory Class:** II

**Product Name:** PerFuse Percutaneous Decompression System

**Physical State:** The delivery cannula consists of a reusable handle assembly (handle, strike plate, slide hammer) and sterile, single-use disposable cannula, trocar rod, plunger rod (stainless steel)

**Technical Method:** Channel is cut into bone by cannula/trocar using handle/hammer. Bone graft material is hydrated, mixed and loaded into the cannula with the piston syringe and delivered through cannula with the syringe and plunger rod.

**Target Area:** Femur, humerus with early stage necrosis

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**

CDO™ System (K072330) consists of a curved delivery cannula, a modified syringe, a flexible plunger and an optional syringe adaptor tip. The Graft Preparation System (piston syringe) was also cleared in (K072330) and can be used to mix and deliver and to enable delivery of blood components and/or bone graft materials through the cannula. These previously cleared predicate devices have the same indications for use as the Perfuse Percutaneous Decompression System.

**Device Description:**

The disposable instrument set is comprised of a sterile, single-use disposable kit containing the stainless steel cannula, trocar rod, and plunger rod. The non-sterile stainless steel handle assembly consists of a reusable handle, slide hammer adapter, slide hammer, and strike cap. The handle assembly is organized in a stainless steel instrument case. All components are made of stainless steel. The strike cap threads onto the handle body and is designed to receive a mallet or hammer strike to drive the trocar point/cannula into bone tissue.

The handle is cannulated to allow the trocar rod to pass through the length of the handle and be contained within the strike cap. The cannula creates a 6.17mm bore diameter hole.

The cannula, trocar rod, and plunger rod all come in two lengths. The cannula is designed for use in accessing the femoral head. The smaller length is designed to access the humeral head. Each cannula has depth lines etched onto the surface to indicate the instrument depth to the operating

surgeon. The cannula and plunger rod and/or syringe (syringe sold separately) are used to deliver blood components and/or bone graft material through the cannula to an orthopedic surgical site.

The gamma-sterilized components are supplied as single use disposables to ensure the cannula is free of debris and the trocar rod is sharp at the beginning of each procedure.

**Indications for Use:**

The PerFuse Percutaneous Decompression System is intended to be used for the delivery of allograft, autograft, and synthetic bone graft material to an orthopedic surgical site. In addition, it is designed to facilitate mixing and pre-mixing of bone graft material with I.V. fluids, blood, plasma concentrate, platelet-rich plasma, bone marrow or other specified blood components deemed necessary by the clinical use requirements.

**Summary of Technologies:** The overall design and processing methods are similar to the predicate device to which substantial equivalence is claimed. The PerFuse Percutaneous Decompression System and CDO System (K072330) have the same intended use of delivering various bone grafting materials through a metal cannula to an orthopedic surgical site. Both devices are used with the Graft Preparation System (K072330).

**Non-Clinical Testing:** Non-clinical laboratory testing was performed. The results indicated that the devices were functional within their intended use.

**Summary Table - Performance Testing - Bench**

Verification Test	Results Summary
1. Cannula Luer Taper Load Test	All 18 syringes maintained a seal throughout the duration of mechanical loading without failure
2. Cannula Luer Taper Load Test – No Axial Restraint	All 18 syringes maintained a seal throughout the duration of mechanical loading without failure.
3. Instrument Integrity in a sawbones simulation	All 6 cannula fully penetrated 1.4 cm into the grade 30 sawbones block. The handle could only be removed from the cannula by releasing the Zimmer-Hudson connection, leaving the cannula in place to facilitate fluid and graft material delivery.
4. Instrument Cadaver Lab Verification Study	Six core decompression procedures were successfully performed using the PerFuse instrument sets (trocar + cannula)
5. Delivery of hydrated graft through PerFuse and CDO cannulas	All acceptance criteria were met. The hydrated graft material was easily expressed from the syringe through the cannula with thumb pressure, at least 80% of the original graft material was delivered, and equivalence between the PerFuse and CDO delivery methods was established.

**Summary Statement**

The PerFuse Percutaneous Decompression System and the CDO System have substantially equivalent characteristics including:

- Ability to deliver hydrated graft material through the cannula
- Utilization of a metal delivery cannula (PerFuse is stainless steel & CDO is aluminum)
- Utilization of syringe and/or bowl for mixing and hydrating bone graft
- Plunger to advance graft material through the delivery cannula into the orthopedic surgical site
- Cannula and plunger rods are single use only
- Identical sterilization of disposables
- Compatibility with the previously cleared Graft Preparation System (mixing/hydrating modified syringe)
- Biocompatible materials conforming to ASTM standards
- Similar Biomet packaging

**Conclusion.** Based on the nonclinical verification testing, results show that both the CDO System and the Perfuse Percutaneous Decompression System delivered at least 80% of the original graft material. The devices have similar designs and the same indications for use. Based on the information provided in this submission, the PerFuse Percutaneous Decompression System is substantially equivalent to the predicate CDO System.

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