APR 3 0 2014

K133600

Coeur, Inc.
Front Load Adapter for CT Injector

510(k) Summary

1. **Submitter:**

Name:	*Coeur, Inc.*
Address:	*100 Physicians Way, Suite 200*
	Lebanon, TN 37090
	Owner/Operator Number: 9038672
Phone:	*(615) 547-7923 (Corporate Office)*
Fax:	*(615) 547-7937 (Corporate Fax)*
Contact:	*Debra F. Manning, Director, Q & RA*
Date:	November 22, 2013

2. **Device:**

Trade/Proprietary Name:	Front Load Adapter for CT Injector for use with Coeur Front Load Syringe
Common/Usual Name:	Adapters for Power Injectors
Classification Name:	Accessory, Injector and Syringe, Angiographic

3. **Legally Marketed Devices to which Substantial Equivalence is claimed:**

Coeur, Inc. Adapters/Pressure Jackets for CT and/or Angiographic Power Injectors (K070798) - Coeur

Medrad Envision CT Injector System, Medrad, K993728

Optivantage DH Injector System with Enhanced Communication (K063503)- Mallickrodt Inc., Liebel-Flarsheim

4. **Device Description:** *The proposed device is a Front Load Adapterfor Liebel-Flarsheim Optivantage DH Injector. As defined by 21 CFR 870.1650, an angiographic injector and syringe is a device that consists of a syringe and a high-pressure injector which is used to inject contrast media into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography. The Coeur adapter is a unit designed to install onto legally marketed power injectors to enable use of the Coeur syringe with such injectors. It includes a component that affixes to the ram of the power injector to adapt it to fit the plunger of the Coeur syringe.*

5. **Intended Use of Device:** For use in adapting Liebel-Flarsheim Optivantage DH Injectors for use with Coeur Front Load Syringes

6. **Summary of Technological Characteristics As Compared to Predicate Devices:** The intended use, the method of use, and the materials of the proposed device are the same as those identified for the legally-marketed predicate Coeur devices as appropriate to the injector. Like the legally-marketed predicate injectors, the proposed device allows for the intended use (injecting contrast media, saline, or other diagnostic fluids into patients) and is made with materials appropriate for its function. The proposed devices position the Coeur Front Load Syringe in front of the ram for use with the injector. Any differences in syringe placement are not significant as the ram is advanced to move the plunger to the full forward position for filling, enabling use with and like the predicate device.

If Substantial Equivalence was based on an Assessment of Performance Data, the following information is also provided:

1. **Nonclinical Tests Submitted:** *Verification of functional performance was achieved which included that the adapter can be properly installed, the syringe will properly load into the adapter, and that the syringe, with the adapter, can be filled and used to inject contrast, saline, or other diagnostic fluids into the patient without affecting the function of the power injectors.*

   Such testing was conducted for the design for use on the Liebel-Flarsheim Optivantage DH Injectors. The installation, the loading, and the injection were all successfully completed. The equipment performed as intended.

2. **Clinical Tests Submitted:** *NA*

3. **Conclusions Drawn from Nonclinical and Clinical Tests Submitted:** *The conclusions drawn from the nonclinical tests demonstrate that the device is as safe and as effective as the legally marketed predicate devices identified.*

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

April 30, 2014

Coeur, Inc.
Ms. Debra Manning
Director, Quality & Regulatory Affairs
100 Physicians Way, Suite 200
Lebanon, TN 37090

Re: K133600
Trade/Device Name: Frontload Adapter for CT Injector
Regulation Number: 21 CFR 870.1650
Regulation Name: Injector and Syringe, Agiographic
Regulatory Class: Class II
Product Code: DXT
Dated: April 10, 2014
Received: April 11, 2014

Dear Ms. Manning:

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 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bram D. Zuckerman -S

Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Front Load Adapter for CT Injector

Indications For Use:

For use in adapting Liebel-Flarsheim Optivantage DH Injectors for use with Coeur Front Load Syringes

Prescription Use _√___ AND/OR Over-The-Counter Use ____
(Part 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)

Bram D. Zuckerman -S
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