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

August 18, 2017

Coeur, Inc.
Priscilla Clinner
Regulatory Specialist
100 Physicians Way
Lebanon, Tennessee 37090

Re: K170431
Trade/Device Name: 200mL Syringe for Stellant Injectors
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II
Product Code: DXT
Dated: July 17, 2017
Received: July 18, 2017

Dear Priscilla Clinner:

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 (DICE) 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 Industry and Consumer Education (DICE) 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,

Kenneth J. Cavanaugh -S

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170431

Device Name
200mL Syringe for Stellant Injectors

Indications for Use *(Describe)*
For use with the Medrad® Stellant® CT Injection System equipped with the appropriate Coeur Fascia and Ram Tip for the injection of contrast media or saline to the vascular system for diagnostic purposes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Coeur, Inc.

200mL Syringe for Stellant Injectors

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:	Priscilla Clinner*, Regulatory Specialist*
Date:	February 10, 2017

2. **Device:**

Trade/Proprietary Name:	200mL Syringe for Stellant Injectors
Common/Usual Name:	200mL Syringe for Stellant Injectors
Classification Name:	Accessory, Injector and Syringe, Angiographic

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

Coeur:

- Coeur Syringes for Nemoto Injectors (K051799) (*Primary Predicate Device)*
- Coeur Front Load Injector Turret & 200mL Front Load Syringe (K960965) (*Secondary Predicate Device)*
- Coeur Adapters for CT, Angiographic, and/or MRI Power Injectors (K070798) *(Secondary Predicate Device)*
- Coeur MR Syringe Dual Pack for Solaris Injectors (K161471) *(Secondary Predicate Device)*

Medrad:

- Syringe included in Medrad® Stellant® CT Injector System with XDS Accessory (K063090) (*Secondary Predicate Device)*

4. **Device Description:**

The 200mL Syringe for Stellant Injectors are syringes / kits intended for use with the Medrad® Stellant® CT Injection System equipped with the appropriate Coeur Fascia and Ram Tip for the injection of contrast media or saline to the vascular system for diagnostic purposes. Each configuration is listed below in the "Models"section and provided sterile. To further define the device, the kits may include (depending on package configuration) extension lines, fill tubes, prime tubes, and spikes. The extension lines are used to connect the syringe to a patient's IV. The prime tube is used for catching fluid while purging air from the extension line. The fill tubes and spikes are used to connect the syringe to contrast media or saline containers for filling. The Fascia (installed on the surface of the injector case and through which the ram/ram tip moves) and the RamTip (connected to the injector ram and to which the syringe is connected), used in adapting the Medrad* Stellant* Injector for use with the Coeur 200mL Syringe for Stellant Injectors are not sterile, and after installation onto the injector, remain installed as long as the Coeur 200mL Syringe for Stellant Injectors is used with the injector. (Cleaning instructions for the Fascia and Ram Tip are provided in the IFU.)

Principle of operation- The syringe plunger is engaged by the equipment ram and moved forward and back for filling and injection purposes.

- Proposed conditions of use – The proposed devices are intended to be sterile for use with the Medrad® Stellant® CT Injection System equipped with the

appropriate Coeur Fascia and Ram Tip for the injection of contrast media or saline to the vascular system for diagnostic purposes. The devices include ISO-594 compatible components for connection with the ISO 594 compatible syringe luer or other components that otherwise press-fit the syringe. All devices included with the syringes are sterilized.

List of devices for which clearance is requested – See "Models" section below for a list of product configurations

5. Models:
The 200mL Syringe for Stellant Injectors will be sold as a single syringe and in a dual pack. The following configurations may be offered:

- C853-3101, 200mL Syringe for Stellant Injectors and Spike
- C853-3102, 200mL Syringe for Stellant Injectors with 60" Coiled Extension Line and Spike
- C853-3103, 200mL Syringe for Stellant Injectors with 60" Coiled Extension Line, Prime Tube and Spike
- C853-3104, 200mL Syringe for Stellant Injectors with Fill Tube
- C853-3105, 200mL Syringe for Stellant Injectors with 60" Coiled Extension Line and Fill Tube
- C853-3106, 200mL Syringe for Stellant Injectors with 60" Coiled Extension Line, Prime Tube, and Fill Tube
- C853-3201, (2) 200mL Syringes for Stellant Injectors with 60" Coiled Extension Y-Line and Spikes
- C853-3202, (2) 200mL Syringes for Stellant Injectors with 60" Coiled Extension Y-Line, and Contrast and Saline Spike
- C853-3203, (2) 200mL Syringes for Stellant Injectors with 60" Coiled Extension Y-Line, Prime Tube and Spikes
- C853-3204, (2) 200mL Syringes for Stellant Injectors with 60" Coiled Extension Y-Line, Prime Tube, and Contrast and Saline Spike
- C853-3205, (2) 200mL Syringes for Stellant Injectors with 60" Coiled Extension Y-Line and Fill Tube
- C853-3206, (2) 200mL Syringes for Stellant Injectors with 60" Coiled Extension Y-Line, Prime Tube, and Fill Tube

The Fascia and RamTip will be sold as a single and a dual Fascia and Ram Tip. The following configurations may be offered:

- C859-3100, Single Fascia and Ram Tip for Stellant Injectors
- C859-3200, Dual Fascia and Ram Tips for Stellant Injectors

6. **Indications For Use:** For use with the Medrad® Stellant® CT Injection System equipped with the appropriate Coeur Fascia and Ram Tip for the injection of contrast media or saline to the vascular system for diagnostic purposes.

7. **Summary of Technological Characteristics as Compared to Predicate Devices:** The intended use (injection of contrast media or saline), the method of use (pressure), and the fluid path materials of the proposed device are the same as the legally-marketed devices.

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

1. **Nonclinical Tests Submitted:** Testing used to verify substantial equivalence including an assessment of Performance Data for the proposed device, including:

a. **Visual Verification of the Products** – Inspection of the product for conformance to visual requirements.
b. **Dimensional Evaluation of the Products** – Inspection of the product to verify dimensional acceptance.
    i. ISO 594-2:1998 – Evaluation to applicable requirements of the ISO 594 standard, including liquid leakage, air leakage, separation force, ease of assembly, resistance to overriding, and stress cracking.
    ii. ISO 7886-2 - Evaluation to applicable requirements of the ISO 7886-2 standard, including cleanliness, limits for acidity and alkalinity, limits for extractable metals, lubricant, tolerance on graduated capacity, graduated scale, piston plunger assembly, and nozzle.
    iii. Dimensional – Evaluation of product to conform to Coeur drawing specifications using gauging and measuring.
    iv. Injector Fit – Evaluation of syringe, fascia and ram tip for fit with the Medrad® Stellant® Injector.
    v. Volume – Evaluation of volume accuracy.
c. **Functional Verification of the Products**: -
    i. Functional Testing was conducted to evaluate the syringe, fascia, and ram tip to function with the Medrad® Stellant® Injector
    ii. Pressure testing was conducted where the syringe was held at 400psi for 10 seconds and the Extension Line was held at 400psi for 2.5 minutes.
    iii. Failure testing followed pressure testing, where syringes and Extension Lines are pressurized under increasing pressure until failure is observed (for reference only).
    iv. Pull testing was conducted on the Extension Lines to verify correct assembly and bonding process during the manufacturing.
    v. Functional testing was conducted on the spike to evaluate the ability of the spike to connect to syringe, bottle port, and bag and allow fluid to flow into syringe.
d. **Age Verification** – Based on use of the same packaging and component material as used in currently marketed devices, the expiration of 1 year is leveraged for the proposed device. Aging study is included and was included in the 510k for predicate device cleared under K051799.
e. **Biocompatibility** – The proposed device is made of the same materials (including, PET, PVC, PC, PE, and ABS) in contact with the fluid path as that cleared under K051799 in formulation, processing, and sterilization, and no other chemicals have been added (e.g. plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.). Further, biocompatibility testing, in accordance with FDA's guidance document titled "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", has been conducted on the proposed device. All test results indicate the suitability of the materials used in the device for the intended purposes: externally communicating, indirect blood path, <24 hours duration.

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

3. **Conclusion Drawn from Nonclinical and Clinical Tests Submitted:** The conclusions drawn from the nonclinical tests demonstrate that the device is substantially equivalent to the predicate devices identified.