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

October 6, 2016

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

Re: K161471
Trade/Device Name: MR Syringe Dual Pack for Solaris Injectors
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: September 2, 2016
Received: September 6, 2016

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 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 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,

Brian D. Pullin -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)*
K161471

Device Name
MR Syringe Dual Pack for Solaris Injectors

Indications for Use *(Describe)*
For use with the Medrad Spectris® Solaris™ MR Injection System 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.

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Coeur, Inc.

MR Syringes for Solaris Injectors

K161471 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 Analyst*
Date:	October 5, 2016

2. **Device:**

Trade/Proprietary Name:	MR Syringe Dual Pack for Solaris Injectors
Common/Usual Name:	MR Syringe Dual Pack for Solaris Injectors
Classification Name:	Accessory, Injector and Syringe, Angiographic

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

Primary Predicate Device
Medrad: Syringe Included in Spectris Solaris MR Injection System (K033247)

Referenced Devices
Coeur:

- Coeur 130mL Syringe (K971712)
- Coeur Syringes for Nemoto Injectors (K051799)
- Coeur 330psi Extension Lines (K120892)
- Coeur MR Syringe Dual Pack (K140469)
- E-Z-EM Empower MR Injector System and Fastload MR Syringe Pack (K062449)

4. **Device Description:** The MR Syringes for Solaris Injectors (65mL and 115mL syringe) falls into the Cardiovascular Devices Category and are classified as Angiographic Syringes within the classification of Angiographic Injectors and Syringes. The syringe is intended for use with Medrad Spectris® Solaris™ MR Injection System to inject diagnostic fluids (such as contrast media and saline) into a patient. The MR Syringe Dual Pack for Solaris Injectors will be sold as a Dual Pack. The following configurations may be offered:

   i. **C853-2201 - 65mL and 115mL Syringe with 96" Coiled extension Y-Line and Fill Spikes**
   ii. **C853-2202 - 65mL and 115mL Syringe with 96" Coiled extension Y-Line and Contrast and Saline Spikes**
   iii. **C853-2203 - 65mL and 115mL Syringe with 96" Coiled extension Y-Line, Prime Tube, and Fill Spikes**
   iv. **C853-2204 - 65mL and 115mL Syringe with 96" Coiled extension Y-Line, Prime Tube, and Contrast and Saline Spikes**

v. **C853-2205 - 65mL and 115mL Syringe with 96" Coiled Extension Y-Line and Fill Tube**
vi. **C853-2206 - 65mL and 115mL Syringe with 96" Coiled Extension Y-Line, Prime Tube, and Fill Tube**

5. **Indications for Use of Device:** For use with the Medrad Spectris® Solaris™ MR Injection System for the injection of contrast media or saline to the vascular system for diagnostic purposes.

6. **Summary of Technological Characteristics as Compared to Predicate Devices:** The intended use (injection of contrast media or saline for diagnostic purposes), the method of use (pressure injection with power injectors), and the fluid path materials (PET barrel, synthetic rubber jacket, extension lines, fill tubes, and spikes) of the proposed device are the same as the legally-marketed devices.

If 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.
      ii. Injector Fit –Evaluation of fit and function with the Medrad Spectris® Solaris™ MR Injection System.
      iii. Volume –Evaluation of volume accuracy.
   c. **Functional Verification of the Products**: -
      i. Pressure testing was conducted where the syringe was held at 350psi for 10 seconds and the Extension Line was held at 400psi for 2.5 minutes.
      ii. Failure testing followed pressure testing, where syringes and Extension Lines are pressurized under increasing pressure until failure is observed.
   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.
   e. **Biocompatibility** – *The proposed device is made of the same materials in contact with the fluid path as that cleared under* K971712 and 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.).

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 substantially equivalent to the predicate devices identified.*