



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 22, 2015

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

Re: K150902

Trade/Device Name: 330psi Extension Y-line With Dual Check Valve
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: September 18, 2015
Received: September 21, 2015

Dear Debra F. 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 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,



for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K150902

Device Name: 330psi Extension Y-Line with Dual Check Valve

Indications For Use:

The 330psi Extension Y-Line with Dual Check Valve is to be used as an interface between an Angiographic, CT, or MR Syringe and a needle catheter for the purpose of delivering diagnostic fluids (such as contrast media and saline) to the vascular system.

Prescription Use √
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Coeur, Inc.

K150902

330psi Extension Y-Line with Dual Check Valve

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 D. F. Manning, Director of Quality Assurance and
Regulatory Affairs*
 - Date: *October 20, 2015*

2. **Device:**
 - Trade/Proprietary Name: 330psi Extension Y-Line with Dual Check Valve
 - Common/Usual Name: 330psi Extension Y-Line with Dual Check Valve
 - Classification Name: Accessory, Injector and Syringe,
Angiographic

3. **Legally Marketed Devices to which Substantial Equivalence is claimed:**
 - Coeur Disposable 330psi Extension Lines K120892

4. **Device Description:** The 330psi Extension Y-Lines with Dual Check Valves will be offered in the following configurations:
 - i. 60” 330psi Extension Y-Line with Dual Check Valve (C405-1569)
 - ii. Short 330psi Extension Y-Line with Dual Check Valve (C405-2042)
 - iii. 60” 330psi Extension Y-Line with Dual Check Valve and Linden Adapters (C405-2155)
 - iv. 96” 330psi Extension Y-Line with Dual Check Valve (C405-2962)

5. **Indications for Use:** The 330psi Extension Y-Line with Dual Check Valve is to be used as an interface between an Angiographic, CT, or MR Syringe and a needle catheter for the purpose of delivering diagnostic fluids (such as contrast media and saline) to the vascular system.

6. **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 material types of the proposed device are the same as the legally-marketed device. As compared to the predicate device, the proposed device is essentially combining the Y-connector and 2 check valves (all of which are separate components in the current legally-marketed devices) into a single component (in the proposed device).

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. **Dimensional Evaluation of the Products** – Inspection of the product to verify dimensional acceptance. (Note: Given no change in the luer connectors, no ISO 594 Testing is required.)
 - b. **Functional Verification of the Products:**
 - i. Crack Pressure and Flow Rate
 - ii. 330psi Pressure Test (Forward and Back)
 - iii. Pressurize to Failure Test
 - iv. Pull Test (Bond)
 - c. **Biocompatibility** - Biocompatibility testing was conducted on the kit to verify it meets the requirements of ISO 10993 for an external communicating, indirect contact, less than 24 hour duration device. The components of the kit met the requirements for such a device. The results are as follows:
 - i. **Cytotoxicity** – Pass (February 12, 2015)
 - ii. **Kligman Maximization Test** – Pass (March 18, 2015)
 - iii. **Intracutaneous Injection Test** – Pass (March 23, 2015)
 - iv. **Systemic Injection Test** – Pass (March 11, 2015)
 - v. **Hemolysis** – Pass (February 18, 2015)
 - vi. **In Vitro Hemocompatibility Assay** – Pass (March 10, 2015)
 - vii. **Rabbit Pyrogen Test** – Pass (February 27, 2015)
 - viii. **Unactivated Partial Thomboplastin** - Pass (March 4, 2015)
 - ix. **Complement Activation Assay** - Pass (March 13, 2015)
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.*