Coeur, Inc.

MR Syringe Dual Pack

JUL 2 8 2014
K140469

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:	*Erin Rheinscheld, Regulatory Analyst*
Date:	February 20, 2014

2. **Device:**

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

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

- Optistar Injection System, Mallinckrodt, K984088
- Disposable CT/MR Syringes for Nemoto Injectors, Coeur, Inc., K051799
- Monoject 60cc Syringes, Sherwood Medical, K852580
- ANT Angiographic Syringes, Shenzhen Ant Hi-Tech, K072696

4. **Device Description:** *The MR Syringe is a pack that includes two 60ml MR Syringes, a 96" coiled Y-Line, and two Lateral Flow Needle Spikes.*

The alternate configuration of the MR Syringe is a pack that includes one 60mL MR Syringe, a 60" Coiled Line, and one Lateral Flow Needle Spike.

Each of the components to be used in the proposed device has been cleared for marketing under previous 510(k) submissions.

5. **Intended Use of Device:** For use with the LF OptiStar Injector for injection of contrast media or saline.

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 exactly the same as those of legally-marketed devices (as they are the same devices packaged together for sterilization).

Given 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 considering both the original and the alternate configurations, including:
    a. **Visual Evaluation of the Products** – Inspection of the product to verify visual acceptance (such as presence of all components).
    b. **Dimensional Evaluation of the Products** – Inspection of the product to verify dimensional acceptance (such as ISO 594 luer compliance).
    c. **Functional Verification of the Products**:
        i. Dynamic testing where the syringe, spike and Y-Line were tested using higher flow rates (which cause higher pressures) to ensure appropriate function when injection was simulated such that the maximum pressure capability of the injector (150psi) was challenged.
        ii. Static testing was also conducted where the syringe was held at the maximum capability of the injector for an extended period of time.
    d. **Age Verification** – Based on the packaging and the components use in the proposed device, the expiration of 3 years is leveraged under the 510k submissions and labeling of products as previously cleared and/or marketed.
    e. **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 (March 13, 2014)
        ii. **Kligman Maximization Test** – Pass (April 10, 2014)
        iii. **Intracutaneous Injection Test** – Pass (March 11, 2014)
        iv. **Systemic Injection Test** – Pass (March 10, 2014)
        v. **Hemolysis** – Pass (March 11, 2014)
        vi. **In Vitro Hemocompatibility Assay** – Pass (April 10, 2014)
        vii. **Rabbit Pyrogen Test** – Pass (March 6, 2014)
        viii. **Unactivated Partial Thomboplastin** - Pass (March 6, 2014)
        ix. **Complement Activation Assay** - Pass (March 9, 2014)

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.*

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

July 28, 2014

Coeur, Inc.
Ms. Erin C. Rheinscheld
Regulatory Analyst
100 Physicians Way, Suite 200
Lebanon, TN 37090

Re: K140469
Trade/Device Name: MR Syringe Dual Pack
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: June 24, 2014
Received: June 25, 2014

Dear Ms. Rheinscheld:

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,

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): K140469

Device Name: MR Syringe Dual Pack

Indications For Use:

For use with the LF OptiStar Injector for injection of contrast media or saline.

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)