COEUR®

K063114

COEUR, INCORPORATED
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Coeur, Inc.

FEB 9 2007

Coeur Medical, a division of Coeur, Inc.
Disposable Transfer Sets with and without Swabbable Valves and/or Check Valves

510(k) Summary

1. **Submitter:**

Name:	*Coeur Medical, a division of Coeur, Inc.*
Address:	*209 Creekside Drive*
	Washington, NC 27889
Phone:	*(615) 547-7923 (Corporate Office)*
Fax:	*(615) 547-7937*
Contact:	*Debra F. Manning, VP, Q & RA*
Date:	*October 5, 2006*

2. **Device:**

Trade/Proprietary Name:	*Disposable Transfer Sets with and without Swabbable Valves and/or Check Valves*
Common/Usual Name:	*Transfer Sets*
Classification Name:	*Fluid Delivery Tubing (a product included in the definition of Intravascular administration set, 21 CFR 880.5440, Product Code FPK or FPA)*

3. **Legally Marketed Devices to which Substantial Equivalence is claimed:**
Fill Tube (K873597) - Coeur
SVTS - Swabable Valve Transfer Set (K031808) - Medrad
Transfer Set (K022431) – Medrad
Contrast Management System (K961794) – Merit
Empower Transfer Set (K041178) – E-Z-EM, INC.

4. **Device Description:**
The Disposable Transfer Sets with and without Swabbable Valves and/or Check Valves are a combination of connectors and accessories, such as clamps, tubing, and spikes, and are used for fluid delivery. The device is designed, like other legally marketed devices, for one end to connect to the syringe to be filled (which is installed on an injector with the plunger forward) and the other end is connected to the bulk container. The plunger is then retracted and contrast, saline, or other diagnostic fluid is drawn into the syringe. The materials and properties of the device are tabled in Item 6, below.

5. Intended Use of Device:

The Disposable Transfer Sets with and without Swabbable Valves and/or Check Valves are for use in transferring contrast, saline, or other diagnostic fluids from bulk containers into syringes. As the table in Item 6 demonstrates, this is consistent with other legally marketed devices.

6. Summary of Technological Characteristics As Compared to Predicate Devices:

Technological Characteristics	Proposed Device	Coeur Device	Medrad Devices	Merit Device	E-Z-EM, INC.	Rationale for Applicable Differences
Intended Use	For use in transferring contrast, saline, or other diagnostic fluids from bulk containers into syringes.	For use in the delivery of contrast media to a syringe.	For use in the delivery of contrast media and saline to a syringe.	For use in the aspiration of contrast media from a container into a syringe and for subsequent injection into the catheter.	Intended to deliver fluid (contrast media or saline) from a container into a CT Power Injector Syringe.	NA – The proposed device is an extension of the existing Coeur device to enable use of contrast, saline, or other diagnostic fluids provided in bulk containers.
Connector Tube	Flexible, clear or tinted, PVC	Polyethylene	PVC	Clear, flexible, plastic	PVC	None
Sterile	Yes	Yes	Yes	Yes	Yes	NA
Sterilization Method	EtO	Same	Same	Same	Same	NA
Components	Combinations of spikes, male and female luers, check valves (is used), stopcocks, clamps, various dust caps, and swabbable valves (Halkey-Roberts)	Tubing formed in the shape of a "J"	Vented spike, dust cap, stopcock, pinch clamp And Vented spike, female luer, swabbable threaded valve (Halkey-Roberts)	Spike assembly with stopcock, fixed male luer, burette chamber and check valves	Female luer, clamp, and spike	NA – No new components or materials or intended uses are being proposed with the proposed device
Connection Method	ISO 594 Luer	Inner diameter of tubing is placed over syringe luer	ISO 594 Luer	ISO 594 Luer	ISO 594 Luer	NA – Device is connected to syringe via luer connection
Multi-Fill Fill Sets	Yes	If required.	Yes	Yes	Yes	NA
Packaging	Sealed Pouch	Same	Same	Same	Same	NA
Shelf Life	3 years	Same	5 years	5 years	3 years	There are no significant differences in the materials or components utilized.

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 has been performed. Bond testing and leak testing were conducted to verify the device performs acceptably. Coeur conducted a product adoption study to verify that the Coeur sterilization cycle is able to sterilize the proposed device with and SAL of 10^{-6}.*

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

3. **Conclusions Drawn from Nonclinical and Clinical Tests Submitted:** *The primary difference between the proposed Coeur devices and other legally marketed predicate devices is that Coeur, who has experience in the production of tubing extension products and has the facilities and equipment for assembly of the proposed devices, will assemble the components to make the proposed devices which will be sterilized in Coeur's sterilization cycle. The results of the testing verify the proposed devices are suitable for their intended use.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Debra F. Manning
Vice President, Quality & Regulatory Affairs
Coeur, Incorporated
704 Cadet Court
Lebanon, Tennessee 37087

FEB 9 2007

Re: K063114
Trade/Device Name: Coeur, Inc. Disposable Transfer Sets with and without Swabbable Valves and/or Check Valves
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPK, FPA
Dated: January 24, 2007
Received: January 25, 2007

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.

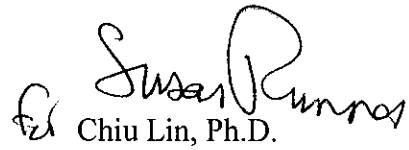
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Coeur, Inc. Disposable Transfer Sets with and without Swabbable Valves and/or Check Valves

Indications For Use:

for use in transferring contrast, saline, or other diagnostic fluids between bulk containers and a syringe

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)

[illegible], General Hospital,
[illegible] Devices

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