K051799

p 1/1

NOV - 2 2005

510(k) Summary

1.	**Submitter:**	Name:	*Coeur, Inc.*
		Address:	*704 Cadet Court* *Lebanon, TN 37087*
		Phone:	*(615) 574-7923*
		Contact:	*Debra F. Manning, VP, Q & RA*
		Date:	*June 30, 2005*

2.	**Device:**	Trade/Proprietary Name:	*Disposable CT/MR Syringes for Nemoto Injectors*
		Common/Usual Name:	*Syringes for CT and MR Injections*
		Classification Name:	*Angiographic Injector & Syringe*

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

Coeurlock Disposable Angiographic Syringe (K965214) - Coeur
Front Load Injector Turret and 200mL FrontLoad Syringe (K960965) - Coeur
Coeur 130mL Syringe (K971712) - Coeur
Syringe for Nemoto 3S Injector, Unimachs Corp., Catalog # 3S Syringe (K983826) – Approved for Legal Marketing for Unimachs Corporation
Medrad Stellant CT Injector System with Imaging System Interface Module (K033881) – Medrad, Inc.
Medrad Microprocessor CT Injection System (K880493) – Medrad, Inc.
CT 9000 Digital Injection System (K912944) – Mallinckrodt Inc., Liebel-Flarsheim Business
OptiStar MR Injection System (K984088) - Mallinckrodt Inc., Liebel-Flarsheim Business
E-Z-EM Percupump 1A (K864227) – E-Z-EM, Inc.
Oz Power Syringe (K973334) – Cardiovascular Innovations

4. **Device Description:** *The Disposable CT/MR Syringes for Nemoto Injectors are plastic, single-use, disposable syringes to be offered in 20mL, 50mL, 100mL and 200mL sizes. The syringes will be offered made of polypropylene or PET – both materials, of which, are available in current legally marketed products. The Nemoto Disposable CT and MR Disposable Syringes are designed for use on Nemoto CT and MR injectors and perform similarly to predicate devices.*

5. **Intended Use of Device:** *The Disposable CT/MR Syringe for Nemoto Injectors is a syringe for the injection of contrast media or saline for CT and MR imaging, for use on Nemoto injectors.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 2 2005

Coeur, Incorporated
c/o Ms. Debra F. Manning
VP, Quality & Regulatory Affairs
704 Cadet Court
Lebanon, TN 37087

Re: K051799
Disposable CT/MR Syringes for Nemoto Injectors
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: II
Product Code: DXT
Dated: September 28, 2005
Received: September 30, 2005

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) 276-0120. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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): K051799

Device Name: Coeur, Inc. Disposable CT/MR Syringes for Nemoto Injectors

Indications For Use:

Syringe for injection of contrast media or saline for CT and MR imaging, for use on Nemoto injectors.

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)

Donna R. Vochmes
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K051799