

OCT - 8 1997

510(k) Summary
Coeur 130ml Syringe with Chlorobutyl Material
April 30, 1997

Official Contact: Christine L. Panzl, Manager Quality Assurance
Coeur Laboratories, Inc.
5301 Departure Drive
Raleigh, NC 27616

Proprietary Name: Coeur 130ML Angiographic Syringe

Common Name: Syringe

Classification Name: Syringe, Angiographic

Predicate Devices: Coeur 130ML Angiographic Syringe

Device Description:

The Coeur syringe is a six piece device (plunger, plunger jacket, barrel, retainer, dust cap, fill tube) which is used in conjunction with power injectors to inject diagnostic fluids associated with angiographic procedures. In particular, the plunger jacket acts as the seal when the plunger is moved to aspirate or inject the contrast media solution. This premarket notification describes the modification to the Coeur syringe, which is a material change to the plunger jacket. The new material Coeur intends to use for the plunger jacket is chlorobutyl.

Intended Use:

USE: for use with Medrad Mark II, III and IV Angiographic Injectors.

Technological Characteristics:

Materials: The Coeur 130ml syringe contains all plastic components molded from chlorobutyl, polycarbonate, polyethylene, and polypropylene.

Packaging/Sterilization: The syringe is individually packaged in a blister tray with Tyvek lid. A case of 50 syringes are sterilized with Ethylene Oxide gas.

Performance Test Data/Conclusions:

Pre-production testing was conducted to evaluate functional performance of the chlorobutyl plunger jacket within the Coeur syringe. Pre-sterilization test results passed all test criteria. Currently the test product is being sterilized so that post sterilization functional performance can be evaluated.

Biocompatibility testing has been conducted on the chlorobutyl material and all test results are acceptable.

At this time the chlorobutyl material performs as well as natural rubber, which is the current material for the plunger jacket. Functional testing and biocompatibility testing have been completed and results are acceptable.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

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Ms. Christine L. Panzel
Quality Assurance Manager
Coeur Laboratories, Inc.
5301 Departure Drive
Raleigh, North Carolina 27604

Re: K971712
Coeur 130ml Angiographic Syringe
Regulatory Class: II (two)
Product Code: DXT
Dated: September 17, 1997
Received: September 22, 1997

Dear Ms. Panzel:

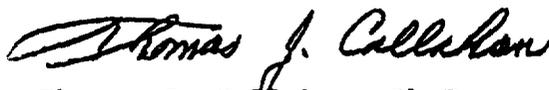
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

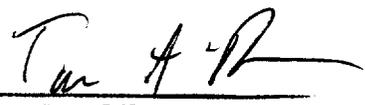
Enclosure

510(k) Number (if known): K971712

Device Name: Coeur 130 ML Angiographic Syringe

Indications For Use:

For use with Medrad Mark II, III, and IV Angiographic Injectors.



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K971712

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)