

# 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) Number is: \_\_\_\_\_

## 1. Applicant Device Information

**Trade/Proprietary Name:** ANT Angiographic Syringes

**Common Name:** Angiographic injector and syringe.

**Classification Name:** Injector and syringe, angiographic

**Device Class:** II

**Product Code:** DXT

**Regulation Number:** 870.1650

**Intended Use:**

ANT Angiographic Syringes are syringes for the injection of contrast media or saline. This syringe is for single use with US legally marketed angiographic injectors.

## 2. Submitter Information

**Manufacturer Name:**

Shenzhen Ant Hi-Tech Industrial Co., Ltd.  
Building 11, Lishan Industrial Park,  
Xinghai Ave, Nanshan District,  
Shenzhen, China

**Contact Person of the Submission:**

Ms. Diana. Hong

Mr. Eric. Chen

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No.19, Lane 999, Zhongshan No.2 Road(S)  
Shanghai, China 20030

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## 3. Predicate Device

K051799

**Trade/Proprietary Name:** Disposable CT/MR Syringes for Nemoto Injectors

**Common/Usual Name:** Syringes for CT and MR Injections

**Classification Name:** Angiographic Injector & Syringe

**Submitter Name:** Coeur, Inc.

**Address:**

704 Cadet Court

Lebanon, TN 37087

**Phone:** (615) 574-7923

**Contact:** Debra F. Manning, VP, Q & RA

## 4. Device Description

The applicant device of ANT Angiographic Syringes are plastic, single-use, disposable syringes to be offered in 10 mL, 12 mL, 20mL, 25ml, 50mL, 60ml, 65ml, 100ml, 115 ml, 125 mL, 130ml, 140ml and 200mL sizes. The syringes will be offered made of polypropylene or PET- both materials, of which, are available in current legally marketed products.

**Variants:** All variants include 7 series as followings:

Series 1: *Model 100101, Model 100102, Model 100103, Model 100201, Model 100202, Model 100203, Model 100204, Model 100301, Model 100302,*

Series 2: *Model 200101, Model 200201, Model 200202, Model 200203, Model 200301,*

Series 3: *Model 300101, Model 300102, Model 300202, Model 300301, Model 300302,*

Series 4: *Model 400101,*

Series 5: *Model 500101, Model 500102,*

Series 6: *Model TR0012,*

Series 7: *Model CS0010, Model CS0020,*

All 8 series follow same design principle, same material, and same intended use. The only differences are volume and the connection (nozzle) to different angiography injector from different manufacturer. The connection differs to fit with US legally Market Angiographic Injectors from company Medrad. The connector difference is only to fit the injector and does not affect the performance of the syringes.

## 5. Substantially Equivalence Determination

### Comparison Analysis:

The Applicant device has the same classification information, intended use, sterilization specifications, performance, biocompatibility, chemical specifications and similar physical and mechanical specifications with the predicate device. The only difference between applicant device and predicate device is some physical specifications variant which is too slight to influence the effectiveness and safety.

### Conclusion:

The applicant device is **Substantially Equivalent (SE)** to the predicate device in terms of Effectiveness and Safety.

## 6. Effectiveness and Safety Considerations

### **Effectiveness:**

All the variant models of the applicant device are evaluated regarding the performance.

### **Safety Considerations:**

With accordance with the Table 1 Initial Evaluation Tests for Consideration and Table 2 Supplementary Evaluation Tests for Consideration in ISO 10993-1:2003(E), Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing, the necessary tests for Biocompatibility Testing includes: Cytotoxicity, Sensitization, Irritation or Intracutaneous Reactivity, Systemic Toxicity (Acute), Haemo-compatibility.

Per 21 CFR 73.3107, Carbazole violet (Pigment Violet 23) (CAS Reg. No. 6358-30-1, Color Index No. 51319) is exempt from the certification requirement of 721(c) of FD&C Act.

**Conclusion:** The all conducted Biological Evaluation Tests are in compliance with the standards of ISO 10993, “Biological Evaluation of Medical Devices”. The compatibility of all the possible skin-contact component material in the finished product meets the requirement of Biocompatibility

The applicant device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the applicant device is determined as safe and effectiveness.



MAY - 2 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Shenzhen Ant Hi-Tech Industrial Co., LTD  
c/o Ms. Diana Hong  
Suite 8D, No. 19, Lane 999  
Zhongshan No.2 Road (S)  
Shanghai, 200030, China

Re: K072696  
Ant Angiographic Syringes, Model 100101,102,103,100201  
Regulation Number: 21 CFR 870.1650  
Regulation Name: Injector and Syringe, Angiographic  
Regulatory Class: Class II (two)  
Product Code: DXT  
Dated: Undated  
Received: April 28, 2008

Dear Ms. Hong:

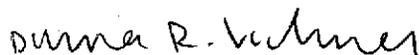
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-3150 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): K072696

Device Name: ANT Angiographic Syringes

Indications for Use:

ANT Angiographic Syringes are syringes for the injection of contrast media or saline. This syringe is for single use with US legally marketed angiographic injectors.

Prescription Use   x    
(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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Anna D. Johnson*  
(Division Sign-Off)  
Division of Cardiovascular Devices

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