K984231

MAY 3 1 2000

510(k) SUMMARY
General Information

Date Prepared	November 23, 1998
Classification	Class II
Trade Name	Angiographic Contrast Management System
Common Name	Intravascular Fluid Delivery Set
Submitter	ACIST Medical System 10250 Valley View Road Eden Prairie, MN 55344 612-941-3507
Contact	Kate Anderson Manager, QA/Regulatory
Predicate Devices	Acist Injection System (K963882) ACIST Medical Systems Merit Contrast Management System (K961794) Merit Medical Systems, Inc. NAMIC Contrast Saving Delivery System (K903493) North American Instrument Corporation, Angiographic System Division

Device Description

The ACIST Medical Systems Angiographic Contrast Management System is an accessory to the ACIST Injection System. It is designed to allow the user to safely use contrast media for multiple procedures. It consists of a two-part kit—Parts A, a non-patient contact kit, and B, a patient contact kit. Part A is initially set up and filled with contrast media. Part B is then attached to Part A via a connector and the system is ready to initiate a procedure. Upon completion of the procedure, Part B is disconnected and discarded. The syringe cap is placed on Part A to maintain sterility between procedures.

The Angiographic Contrast Management System is provided sterile and is intended for single use only.

Indication

The Acist™ Injection System is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures. The Angiographic Contrast Management System allows the user to safely use contrast media for multiple procedures.

Technological Characteristics

The Angiographic Contrast Management System is designed to prevent patient contacting fluids from contaminating the fluid contained within the dual port syringe and contrast media container. Like the predicate Merit and Namic products, the Angiographic Contrast Management System is designed with one-way check valves to prevent retrograde flow.

As with the Namic product, Biological Challenge tests were conducted demonstrating the ability of the device to maintain the sterility of the contrast media and syringe, allowing continued used of those components. Pressure testing verified the interconnect between Parts A and B. Packaging validation testing verified the modified packaging configuration.

Summary

In summary, the above listed predicate devices and the ACIST Angiographic Contrast Management System are substantially equivalent based on design, performance characteristics, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 1 2000

Mr. Carl M. Beaurline
Vice President
Quality Assurance/Regulatory Affairs
Acist Medical Systems, Inc.
7450 Flying Cloud Drive, Suite 150
Eden Prairie, MN 55344

Re: K984231 and K991103
Trade Name: Acist™ CMS-2000 Angiographic Injection System with Contrast Management
Regulatory Class: Class II
Product Code: DXT
Dated: November 25, 1998 and March 26, 1999
Received: November 25, 1998 and April 1, 1999

Dear Mr. Beaurline:

We have reviewed your Section 510(k) notifications of intent to market the device referenced above and we have determined the device is substantially equivalent 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 notifications. 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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

PART A - INDICATIONS FOR USE FORM

510(k) Number: **K984231**

Device Name: **Acist™ CMS-2000 Angiographic Injection System with Contrast Management**

Indications for Use:

The Acist™ CMS-2000 Angiographic Injection System with Contrast Management is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____
(Optional Format 1-2-96)