

2/11/99

K984058

510(k) Summary

ACIST Angiographic Injector System

General Information

Classification	Class II
Trade Name	ACIST Angiographic Injector System
Submitter	Acist Medical Systems 10250 Valley View Drive Eden Prairie, MN 55344 (612) 941-3507
Contact	Kate Anderson Manager, QA/regulatory

Predicate Devices

Angiographic Injector System from Acist Medical. K963982

Device Description

This device is a modification to the Acist Angiographic Injector System. The modification is a means to use various types of radiographic contrast containers with the injector system. The present system is optimized for use with bottles of radiographic contrast. The modification is a hanger style holder and will work with the more recent types of radiographic contrast containers, such as bags, as well as bottles. The modification is designed to work with all types of radiographic contrast containers including bags and bottles of various sizes.

Reason for Modification

The present Acist Angiographic Injector System holds contrast bottles by the neck of the bottle.

Since the design of the existing system, contrast manufacturers have started distributing contrast in bags.

To accommodate all the presently known contrast containers, a new container holder was developed. The contrast holder resembles an IV style hanger.

Device Description of Acist Angiographic Injector System

Note: This is a description of the use of the system which is provided for background. This description does not specifically describe the modification which is the subject of this 510(k)

The ACIST is an angiographic injector system which supplies radiographic contrast material to a catheter at a clinician determined variable flow rate which can be remotely and continuously varied by the user. The system includes a motorized syringe pump which delivers radiographic contrast material to tubing which is connected to a angiographic catheter. The clinician controls the flow rate of radiographic contrast material from the pump to the catheter with a hand actuated proportional controller. By operating the hand control, the user can vary a command signal in order to adjust the flow rate of radiographic contrast material from the pump to the outlet during the operation of the pump. The remote hand control allows the clinician to interactively adjust flow rate (and thus volume of material delivered to the patient) while observing the angiographic procedure (for example on a fluoroscope monitor).

The system includes a remote hand controller which is responsive to the command signal from the clinician. Based upon that command signal, the controller controls flow rate of the radiographic contrast material from the pump to the outlet.

The system also includes a specifically designed disposable kit. The kit includes a syringe and valve assembly, injection manifold assembly, high pressure assembly, tubing assembly and associated caps and connectors. The kit is intended to provide all components necessary to perform an angiographic study.

Device Description of Contrast Hanger for the Acist Angiographic Injector System

The modification consists of:

- a new holder for the contrast container. The new holder which resembles a saline bag hanger and will accommodate various form factors of contrast media containers including bags and various sizes and shapes of bottles.
- a new mechanical means to support the contrast empty sensor
- a new sensor to detect the presence/absence of contrast
- minor software changes to support the new sensor

Intended Use

Note: There is no change to the indications for use.

The ACIST System from Invasatec is intended to be used for the controlled infusion of radio-opaque contrast media for angiographic procedures.

Testing

Testing of the modification included:

- functional testing that the change functions correctly for all types of contrast containers. This included mechanical fit with the various contrast containers, that the sensor correctly detects contrast present/not present, and that the functions of the system associated with these changes (fill syringe with contrast) function correctly.
- Testing to assure that the changes do not adversely affect the safety of the product. Testing was done according to selected portions UL2601-1/IEC 601-1 General Requirements for Medical Electrical Equipment, including:
 - test that there are no sharp edges which will damage surgical gloves or user
 - test according to the 10 degree tip test
 - mechanical strength requirements
 - rough handling (drop, roll) requirements
- Reliability/life testing of selected portions of the new design including:
 - sensor door life test
 - operation after rough handling (previously described)
- Functional testing with identified environmental constraints

including:

- operation in the presence of dried contrast
- operation under various ambient light conditions
- operation after rough handling (previously described)
- Regression testing of applicable portions of the system test to assure that performance has not been affected.
- Software testing including:
 - Code review of affected units
 - Testing of the changes

All testing of the product yielded acceptable results.

Summary of Substantial Equivalence

The ACIST Angiographic Injector System, with contrast hanger (proposed model number CL100H) is substantially equivalent to the ACIST Angiographic Injector System, Model CL100 basic overall design, methods of manufacturing, and materials used are substantially equivalent.

The clinical indications for use are identical to the predicate devices.

Acist Medical Systems believes the ACIST Angiographic Injector System, with contrast hanger is substantially equivalent to existing marketed devices.

Therefore, due to the similarity of design and construction, the test results and the identical indications for use to other angiographic injectors, Acist Medical Systems believes this product does not raise any new safety or effectiveness issues.



FEB 11 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kate Anderson
Acist Medical Systems
10250 Valley View Drive
Eden Prairie, MN 55344

Re: K984058
Trade Name: ACIST Angiographic Injector
Regulatory Class: II
Product Code: IZQ
Dated: October 30, 1998
Received: November 13, 1998

Dear Ms. Anderson:

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 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. 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.

Page 2 - Ms. Kate Anderson

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) 594-4639. 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" (21CFR 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,



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

Indications for Use

Center for Devices and Radiological Health

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510(k) Number (if known): K984058

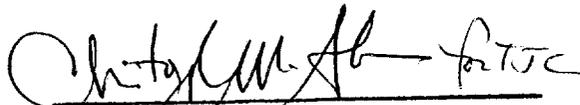
Device Name: ACIST Angiographic Injector System with

Indications for Use: Contrast Hanger

The ACIST system 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

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