K991103

MAY 3 1 2000

510(k) Summary

ACIST CMS2000
Angiographic Contrast Management Injector System

General Information

Classification	Class II
Trade Name	ACIST Angiographic Contrast Management Injector System
Submitter	Acist Medical Systems 7450 Flying Cloud Drive Eden Prairie, MN 55344 (612) 941-3507
Contact	Ed Miller Vice President, Operations

Predicate Devices

Angiographic Injector System from Acist Medical	
Models CL100	#K963982
CL100H	#K984058

Device Description

This device is a variation of the Acist Angiographic Injector System (CL100 & CL100H). The CMS2000 is designed to be used with the CMS disposable kits. The CMS2000 and the disposable kits allow the user to maintain a reservoir of contrast between cases.

Reason for Modification

The CMS2000 is designed to accommodate the CMS disposable kit. The disposable kit allows the user to draw from a single reservoir of contrast for more than one case.

Device Description of the Acist CMS 2000 Contrast Management System

The CMS 2000 system includes an electro-mechanical powered device consisting of a power supply, pump head (syringe pump), and control panel with a disposable hand-held proportional remote control device. Also included is a disposable device containing a two port syringe body, syringe plunger, spool valve manifold, high pressure tube, three-way stopcock, pressure transducer dome, tubing, saline tubing and spike.

Contrast media, saline, and catheters are not included.

The pump head houses the electrical controls and sensing electronics for the system, together with the motors which drive the piston which controls contrast flow, and the peristaltic pump which controls saline flow. The control panel (console/user interface) provides control and display through a touch sensitive LCD panel, which the user may enter, control settings and monitors the operational state of the system.

The power supply houses the transformer and other filtering and power conditioning electronics for the device. The power supply is a stand-alone unit, which connects to the pump head via a cable assembly. The power supply may be remotely mounted if required.

The control panel houses a LCD display, resistive element touch screen, conditioning electronics, standby switch and speaker. The user enters injection parameters from the control panel touch screen. It connects to the injector head via a multi-conductor cable.

The hand control is connected to the display console. The hand-held control includes mechanisms for variable, proportional flow rate control and mechanisms for initiation and termination of other functions, such as saline dispense. The flow rate control provides the user with a means that can be manipulated (squeezed, moved, pushed, etc.) by the user to provide a variable command signal to the control panel to provide a continuously variable injection rate. It is expected that different configurations of the hand controller may be provided to accommodate a broad range of users.

The mounting chamber projects from the injector head. The mounting chamber is a clear material supported by a metal structure, and includes a pivoting door, reservoir holder, back light and sensing electronics.

The cart assembly contains a mechanism to assure that only CMS disposable kits are used with the CMS 2000. The cart/mounting system is a unique set of components, which allow for the attachment of the system's subsystems to each other or other objects depending on the application. The mounting system allows the user to optimally position subsystem components in the cath lab with a minimal amount of effort. Various mounting systems, such as bed mount and boom mount, possibly combined with a cart mount are anticipated as future system enhancements.

When the catheter is in place in the patient, and an injection of radiographic contrast material is not taking place; the pressure transducer monitors the distal tip pressure of the catheter. The patient's blood pressure is measured through the column of fluid that extends from the catheter, tube, patient port, manifold, transducer/saline port, and tubing.

The peristaltic pump supplies saline solution from the bag to the saline port. When the peristaltic pump is operating to supply saline solution, the saline solution is supplied through the manifold to the patient port and then through the tube to the catheter.

The initial setup of the injector requires both Part A and Part B installed and primed. Setup screens lead the user through the installation process. For subsequent procedures, only the Part B requires replacement up to the recommended number of uses for Part A. Once the system is set up with all the disposable items installed, the door is closed, and the syringe body is filled with contrast material and purged of air. The user (typically a physician) enters the parameters that will apply to the injection of radiographic contrast material into the system. The system can be operated as a user interactive system or a fixed rate delivery system. For interactive use, parameters entered are the maximum amount of radiographic contrast material to be injected during any one injection, the maximum flow rate of the injection with the hand controller fully depressed, the maximum pressure developed within syringe body, and the maximum rise time or acceleration of the injection. To actuate an injection of contrast material, the user operates the remote control of the hand controller. Within the preset parameters, the system causes the flow rate of the injection to increase as the force or distance of travel of the trigger is increased.

Typically, the user will meter the amount and rate of contrast material injected based upon continuous observation of the contrast outflow into the structure being injected using fluoroscopy or other imaging methods. The system allows the user to tailor the contrast injections to the needs of the patient, thereby maximizing the quality of the procedure, increasing the safety, and reducing the amount of contrast material required to perform the examination. In the fixed rate mode, the injector will inject a fixed rate of contrast media.

The electrical control system includes multiple digital computers which receive input signals from remote control and control panel through interface, and provides signals to display operation data, alerts, status information and operator prompts.

The computer controls the motion of the plunger through a motor drive circuit that includes motor, motor amplifier, optical encoder, potentiometer, and A/D converter.

The motor amplifier provides a drive signal to motor in response to Control Voltage, Fwd/Rev, and Brake signals from the computer and a speed feedback signal from an optical encoder. The outputs of the optical encoder and potentiometer are supplied to the computer through A/D converter as Speed Monitor and Position Monitor signals. These allow the computer to check motor speed, motor direction, and position (volume is a calculated value).

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~~ K991103

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)