

K963982

Attachment G

DEC - 5 1997

510(k) Summary

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ACIST Angiographic Injector System

General Information

Classification	Class II
Trade Name	ACIST Angiographic Injector System
Submitter	Invasatec Corporation 10180 Viking Drive Eden Prairie, MN 55344 (612) 941-3507
Contact	Doug Duchon Vice President

Predicate Devices

Mark V from Medrad, Inc. K822536.
Mark V+ from Medrad, Inc.

Device Description

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.

Intended Use

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

Testing

The materials used in the construction of the ACIST disposable angiographic kit are well known materials widely used in the medical industry. All materials are certified from the vendor as biocompatible based on compliance with USP Class VI and/or ISO 10993. All materials are biocompatible and are suitable for this application.

Physical testing of the system included: dimensional inspection, bond strength testing, burst pressure, flow rate capability, and performance under simulated conditions. Electrical safety testing was performed per IEC 601-1 and electromagnetic compatibility testing per IEC 601-1-2. All testing of the product yielded acceptable results.

Summary of Substantial Equivalence

The ACIST System components are constructed of the same or substantially equivalent materials as the predicate products. The sizes and configurations available along with the packaging and sterilization methods are also equivalent.

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

Therefore, due to the similarity of materials to other angiographic injection systems, the test results and the identical indications for use to other angiographic injectors, Invasatec believes this product does not raise any new safety or effectiveness issues.



DEC - 5 1997

Mr. Doug Duchon
V.P. Product Development
Invasatec, Inc.
10180 Viking Lane
Eden Prairie, Minnesota 55344

Re: K963982
Invasatec ACIST Angiographic Injector
Regulatory Class: II (two)
Product Code: DXT
Dated: September 9, 1997
Received: September 10, 1997

Dear Mr. Duchon:

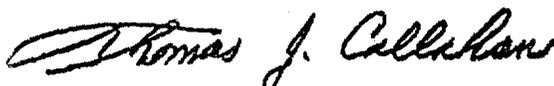
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K963982

Device Name: Invasatec ACIST Angiographic Injector

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.

Tam A. Ryan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K963982

(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)