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acist MEDICAL SYSTEMS

510(k) SUMMARY
Acist *PLUS 4*™ Angiographic Catheter

Applicant's Name and Address:

Acist Medical Systems, Inc.
7450 Flying Cloud Drive
Suite 150
Eden Prairie, MN 55344

Name of Contact Person:

Carl M. Beaurline
Vice President, Quality Assurance / Regulatory Affairs

Telephone and Fax Numbers:

Telephone – (612) 995-9319
Fax – (612) 941-4648

Address of Contract Manufacturing and Sterilization Sites:

Manufacturing: MedAmicus Incorporated
15302 Highway 55 West
Minneapolis, MN 55447

Sterilization: STERIS Corporation
380 90th Avenue N.W.
Minneapolis, MN 55433

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Proprietary Name:	Acist *PLUS 4*™ Angiographic Catheter
Common Name:	Angiographic Catheter
Classification Name:	Diagnostic Intravascular Catheter
Classification Number:	870.1200
Class:	II
Classification Panel:	Cardiovascular
Product Code:	DQO

Brief Description:

The **Acist *PLUS 4*™ Angiographic Catheter** is intended for use in the delivery of radiopaque contrast media to selected sites in the vascular system. It is a single-lumen catheter manufactured primarily from a radiopaque plastic tube that has an encapsulated stainless steel wire braid to provide strength for injection pressures up to 8275 kPa. The proximal end of the device incorporates a strain relief with a female plastic Luer hub for injection to the injection source. The stem and tip sections are radiopaque and are permanently formed to a variety of shapes to facilitate use in various parts of the patient's vasculature. The non-tapered soft distal tip has end and multiple side-holes to balance the injection force and stabilize tip position.

The device is packaged in a Tyvek-to-poly pouch, sterilized by a validated Ethylene Oxide sterilization cycle, and sold for single use only within a 24-month shelf life.

Predicate Device:	Acist 4 French Angiographic Catheter, K012983

Indications for Use:

The Acist PLUS 4™ Angiographic Catheter is intended for use to deliver radiopaque contrast medium to selected sites in the vasculature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 26 2002

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: K021015
Acist *PLUS 4*™ Angiographic Catheter
Regulation Number: 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II (two)
Product Code: 74 DQO
Dated: March 19, 2002
Received: March 29, 2002

Dear Mr. Beaurline:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(k) Number: K021015

Device Name: **Acist *PLUS 4*™ Angiographic Catheter**

Indications for Use:

The Acist PLUS 4™ Angiographic Catheter is intended for use to deliver radiopaque contrast medium to selected sites in the vasculature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular Devices
510(k) Number K021015

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)