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5. Summary of Safety and Effectiveness

Submission Date	November 25,2009
Submitter	ACIST Medical Systems, Inc. 7905 Fuller Road Eden Prairie, MN 55344
Submitter Contact	Mr. Al Saalabi Vice President of Regulatory Affairs and Quality Assurance ACIST Medical Systems, Inc. (952) 995-9315 (952) 941-4648 (fax) al.saalabi@acistmedical.com
Manufacturing Site	ACIST Medical Systems, Inc. 7905 Fuller Road Eden Prairie, MN 55344 USA
Official Contact	Mr. Al Saalabi Vice President of Regulatory Affairs and Quality Assurance ACIST Medical Systems, Inc. (952) 995-9315 (952) 941-4648 (fax) al.saalabi@acistmedical.com

JAN 15 2010

Trade Name	Adagio™ Retracting ECG Lead Wires
Proprietary Name:	Adagio™ Retracting ECG Lead Wires
Common Name	ECG Lead Wires
Classification Name	Patient Transducer and Electrode Cable (including connector) 21CFR 870.2900, Product Code DSA
Classification Regulation	21 CFR §870.2900
Classification	II
Product Code	DSA

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Substantially Equivalent Devices	Company Name	Predicate 510(k) Number	Predicate Manufacturer / Model
	Merit Cables Incorporated	K942321	Various Patient Monitoring Cables
Proposed Device Description	• The Adagio™ Retracting ECG Lead Wires are standard five lead wire set that incorporate retractors to facilitate the handling of the lead wires and are: • ANSI/AAMI EC 53: 1995 (R) 2001 Compliant • AAMI EC 13: 2002 (R) 2007 Color Code compliant		

Intended Use: The Adagio™ Retracting ECG patient lead wires are used to connect electrodes and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a health care professional.

CAUTION: Federal (USA) law restricts sale of the Adagio™ Retracting ECG Lead Wires to or on the order of a physician.

Technology Comparison: The Adagio™ Retracting ECG Lead Wires has identical performance and technological characteristics of common non retractable ECG patient lead wires used extensively in the medical industry as well as the legally marketed predicate, cleared under 510(k) K942321..

Summary of Performance Testing:

Sterilization Validation: Not Applicable: The Adagio™ Retracting ECG Lead Wires are not provided sterile.

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Shelf Life Testing	Not Applicable: The Adagio™ Retracting ECG Lead Wires; are intended to be reusable.
Biocompatibility Testing	Not Applicable: The Adagio™ Retracting ECG Lead Wires do not have patient contact. Therefore they do not require biocompatibility testing.
Electrical Safety Testing	The Adagio™ Retracting ECG Lead Wires were tested and found to comply with all required patient safety testing including with the following applicable Standards: • 21 CFR 898.12 • IEC 60601-1, Sub clause 56.3 (c) • ANSI/AAMI EC 53: 1995 (R) 2001 Test results confirm that the Adagio is safe and effective for its intended use.
Performance Testing - Bench	Bench testing was conducted on the Adagio™ Retracting ECG Lead Wires according with established protocols and test results confirm that the final product met the requirements for the safety and performance standards and its intended use.
Performance Testing - Animal	Animal performance testing is not required and was not performed to demonstrate safety and effectiveness of the Adagio.
Performance Testing - Clinical	Clinical performance testing is not required and was not performed to demonstrate safety and effectiveness of the Adagio.

Conclusion

- The Adagio™ Retracting ECG Lead Wires are equivalent to the predicate lead wire devices cleared to market under 510(k) K942341.
- Electrical safety and bench testing confirms the device performs as intended.
- The proposed device does not raise new issues of safety and effectiveness.
- The proposed device is deemed safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 15 2010

Acist Medical Systems, Inc.
c/o Mr. Al Saalabi
Vice President of Regulatory Affairs and Quality Assurance
7905 Fuller Road
Eden Prairie, MN 55344

Re: K093657
Trade/Device Name: Adagio™ Retracting ECG Lead Wires
Regulatory Number: 21 CFR 870.2900
Regulation Name: Patient Transducer and Electrode Cable (Including Connector)
Regulatory Class: II (two)
Product Code: 74 DSA
Dated: November 25, 2009
Received: November 25, 2009

Dear Mr. Saalabi:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K093657

Device Name: Adagio™ Retracting ECG Lead Wires

Indications for Use: The Adagio™ Retractable ECG patient lead wires are used to connect electrodes and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a health care professional.

CAUTION: Federal (USA) law restricts sale of the Adagio™ ECG Leads to or on the order of a physician.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE

Donna R. Vochmer
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093657