

DEC 11 1998

K983649

**510(k) Summary of Safety and Effectiveness Information  
MAX-ACT Activated Clotting Time Test Tube**

Array Medical, Inc.  
One Harvard Way, Suite 5  
Hillsborough Campus  
Somerville, NJ 08876  
908-707-8872

Contact: Michael F. Corsello, 908-707-8872

Date: October 12, 1998

Device Names:

Trade Names: MAX-ACT

Common Name: Activated clotting time test

Classification Name: Activated whole blood clotting time tests

Legally Marketed Device:

Array Medical Actalyke C-ACT test tube, K964609.

Device Description:

The MAX-ACT Activated Clotting Time test tubes utilize a "cocktail" of particulate activators (including celite, kaolin, and glass particles) and is intended for use in the measurement of the activated clotting time test (ACT) on Actalyke Models A1, A1P, A2, A2P, and Hemochron® Models 400, 401, 800, 801 and 8000.

Intended Use:

The MAX-ACT Activated Clotting Time test tubes are intended for use in the measurement of the activated clotting time test (ACT) on Actalyke Models A1, A1P, A2, A2P, and Hemochron® Models 400, 401, 800, 801 and 8000.

Performance Data:

Substantial equivalence of the MAX-ACT ACT test tubes to the Array Medical Actalyke C-ACT is supported by an in-house study.

Whole blood was obtained from normal donors and heparinized in vitro up to 10.0 units of heparin/ml. Currently, the most common method for heparin monitoring in these heparinization ranges are the celite and kaolin based ACT tests (C-ACT (celite) and K-ACT (kaolin) (0.0-5.0 units/ml – 600 seconds) and HEMOCHRON CA510 (celite) (up to 600 seconds), Hemochron FTKACT (kaolin) (up to 600 seconds). The correlation of the MAX-ACT Activated Clotting Time test tube and various combinations of Actalyke and Hemochron instruments and ACT tubes were determined.

In-vitro heparin sensitivity curves were generated from three normal, healthy volunteers. Samples (n=72) were generated by adding increasing amounts of heparin to aliquots of normal donor blood. MAX-ACT Activated Clotting Time Tests were performed.

A positive correlation between the MAX-ACT and the C-ACT/FTCA510 was demonstrated when paired testing was performed. The MAX-ACT demonstrated a positive correlation with the C-ACT tubes ( $r=0.97$ ,  $p=.0001$ ,  $n=72$ ) (Figure E1). The data is shown in Table E1.

Studies were also conducted clinically at numerous institutions. A total of 330 paired blood samples were collected from patients (including adult bypass, pediatric bypass, and cardiac catheterization) before, during, and following heparinization. The patients were divided into four discrete groups. These groups consisted of:

**Study Group 1. Bypass Patients:** Results obtained using a reference celite-based ACT test (C-ACT/FTCA510) were compared to those obtained using MAX-ACT test tubes. A total of 239 patient samples were collected from bypass patients (n=30) before, during, and following heparinization during cardiopulmonary bypass. The data yielded a correlation coefficient of  $r^2=0.82$  (Figure E2) and  $r^2=0.87$  (Figure E3) when samples from the reference group were omitted which were outside the published linear range for the reference tube. The data is shown in Table E2.

**Study Group 2. Aprotinin Bypass Patients:** Results obtained using a reference kaolin-based ACT test (ACTII/K-ACT/FTKACT) were compared to those obtained using MAX-ACT test tubes. A total of 28 patient samples were collected from bypass patients receiving antifibrinolytic therapy (aprotinin) (n=6) before, during, and following heparinization during cardiopulmonary bypass. The data yielded a correlation coefficient of  $r^2=0.89$  (Figure E4). The data is shown in Table E3.

**Study Group 3. Pediatric Bypass:** Results obtained using a reference celite-based ACT test (FTCA510) were compared to those obtained using MAX-ACT test tubes. A total of 41 patient samples were collected from pediatric bypass patients (n=5) before, during, and following heparinization during cardiopulmonary bypass. The data yielded a correlation coefficient of  $r^2=0.86$  (Figure E5). The data is shown in Table E4.

**Study Group 4. Catheterization Patients:** Results obtained using a reference celite-based ACT test (FTCA510) were compared to those obtained using MAX-ACT test tubes. A total of 22 patient samples were collected from cardiac catheterization patients (n=10) before, during, and following heparinization during the procedure (diagnostic and interventional). The data yielded a correlation coefficient of  $r^2=0.88$  (Figure E6). The data is shown in Table E5.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. Michael F. Corsello  
Array Medical, Inc.  
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Somerville, New Jersey 08876

Re: K983649  
Trade Name: MAX-ACT  
Regulatory Class: II  
Product Code: JBP  
Dated: October 14, 1998  
Received: October 16, 1998

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.

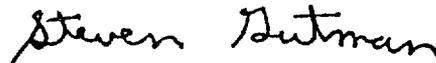
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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

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) 594-4588. 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,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Statement of Indications For Use**

510(k) Number: K983649

Device Name:

MAX-ACT™ Activated Clotting Time Tubes

"Indications For Use" -

The MAX-ACT Activated Clotting Time test tubes are intended for the measurement of the activated clotting time (ACT) test on Actalyke Models A1, A1P, A2, A2P, and on Hemochron Models 400,401,800,801, and 8000.



**(Division Sign-Off)**  
**Division of Clinical Laboratory Devices** K983649  
**510(k) Number** \_\_\_\_\_

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(per 21 CFR 801.109)

or

Over-The-Counter Use