Section 3

MAR 8 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
ACTICHROME® Heparin (anti-fXa)
Heparin Assay (per 21CFR864.7525)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K013318

Submitted by:
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Contact:
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Field Trial Coordinator
Phone: 203 661-0000

Summary Revised:
February 26, 2002

Name of the Device:
ACTICHROME® Heparin (anti-fXa)
Product No. 832

Classification:
864.7525 Heparin Assay, Class II
Product Code KFF

Predicate Device:
Spectrolyse® Heparin (Xa) K923499

Intended Use:
ACTICHROME® Heparin (anti-fXa) is a chromogenic assay intended for the quantitative determination of unfractionated and low molecular weight heparins in human plasma. The assay measures the inhibition of factor Xa (fXa) activity by the various heparins. The Electra 900C® was used to determine performance data.

Summary of Substantial Equivalence:
ACTICHROME Heparin (anti-fXa) kit is substantially equivalent to the commercially available predicate device, Biopool Spectrolyse® Heparin (Xa), manufactured by Biopool International, Ventura, CA, in performance and intended use.

Summary of Performance Data:

Method Comparison
Method comparison studies versus the predicate device were performed with two lots of ACTICHROME Heparin (anti-fXa). The regression statistics in Table 1 indicate a positive correlation between the ACTICHROME Heparin (anti-fXa) assay and the predicate device.

Table 1: Correlation (Y= ACTICHROME, X= predicate device)

ACTICHROME Heparin (anti-fXa)	N	Regression Equation	R	Sy.x (ng/ml)	Sample Range (ng/ml)
Lot 007 (unfractionated Heparin)	92	Y= 0.843X + 0.003	0.913	0.07	0.01-0.8
Lot 010 (unfractionated Heparin)	40	Y= 0.765X--0.009	0.859	0.08	0.00-0.8
Lot 010 (LMW Heparin)	42	Y= 1.363X--0.139	0.895	0.14	0.30-1.3

Precision
Lot 007 precision studies evaluated intra-assay and inter-assay variability with 2 control samples run in quadruplicate over 20 runs (N = 80 per control). Lot 010 evaluated intra-assay and inter-assay variability with 2 control samples run in quadruplicate over 10 runs (N = 40 per control). Lot 010 evaluated unfractionated heparin and low molecular weight heparin. The results are provided in Tables 2a and 2b.

Table 2a: Precision using unfractionated heparin

ACTICHROME Heparin (anti-fXa)Lot 007	Mean (U/ml)	Intra-Assay CV%	Inter-Assay CV%
Hepanorm Control 6	0.44	3.3	4.1
Hepanorm Control 3	0.25	5.6	4.8

Table 2b: Precision using unfractionated heparin and low molecular weight heparin

ACTICHROME Heparin (anti-fXa) Lot 010	Mean (U/ml)	Intra-Assay CV%	Inter-Assay CV%
Control Plasma spiked with 0.5 U/ml UFH Heparin	0.51	2.8	4.6
Control Plasma spiked with 0.25 U/ml UFH Heparin	0.22	3.6	10.6
Control Plasma spiked with 0.5 U/ml LMW Heparin	0.48	2.9	6.2
Control Plasma spiked with 0.25 U/ml LMW Heparin	0.24	5.1	9.3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 8 2002

Mr. John Berryman
Director of Regulatory Affairs
American Diagnostica Inc.
222 Railroad Avenue
Greenwich, CT 06830

Re: k013318
Trade/Device Name: ACTICHROME® Heparin (anti-fXa)
Regulation Number: 21 CFR 864.7525
Regulation Name: Heparin assay
Regulatory Class: Class II
Product Code: KFF
Dated: February 26, 2002
Received: February 27, 2002

Dear Mr. Berryman:

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 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" (21CFR 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,

Steven Gutman

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

Section 2

STATEMENT OF INDICATIONS FOR USE

Applicant: American Diagnostica Inc.

510(k) Number: K013318

Device: ACTICHROME® Heparin (anti-fXa)

Indications for Use:

ACTICHROME® Heparin (anti-fXa) is a chromogenic assay intended for the quantitative determination of unfractionated and low molecular weight heparins in human plasma. The assay measures the inhibition of factor Xa (fXa) activity by the various heparins. The Electra 900C® was used to determine performance data.

This kit is for *in vitro* diagnostic use.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K013318