Section 3

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
ACTICLOT® Protein S
Quantitative Factor Deficiency Test (per 21CFR864.7290)

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: K012386

Submitted by:
American Diagnostica Inc.
222 Railroad Avenue
Greenwich, CT 06830
Phone: 203 661-0000
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Contact:
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Field Trial Coordinator
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Summary Prepared:
July 8, 2001

Name of the Device:
ACTICLOT Protein S
Product # 843L

Classification Name(s):
864.7290 Factor Deficiency Test, Class II
81GGP Test, Qualitative and Quantitative Factor Deficient

Predicate Device:
BIOCLOT Protein S–300 ACT K955738

Intended Use:
ACTICLOT Protein S is an *in vitro* diagnostic clotting assay for the quantitative determination of Protein S activity in human plasma.

Summary of Substantial Equivalence:

ACTICLOT Protein S is substantially equivalent to the commercially available predicate device (BIOCLOT Protein S–300 ACT, 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 different lots of ACTICLOT Protein S. The regression statistics in Table 1 indicate a positive correlation between the ACTICLOT assay and the predicate device.

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

ACTICLOT Lot	n	Regression Equation	R	Sy.x (% Activity)	Sample Range (% Activity)
1	78	Y = 0.91X + 17.2	0.868	12.3	22-114
2	37	Y = 1.06X - 7.5	0.916	14.2	18-117

Precision
Precision studies evaluated intra-assay and inter-assay variability with 2 control samples run in replicates of 4 over 20 runs (n = 80 per control).

Table 2: Precision

Control Level	Mean (% Activity)	Intra-Assay CV%	Inter-Assay CV%
Normal	86.8	3.0	5.9
Abnormal	41.9	2.3	5.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 4 2001

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

Re: k012386
Trade/Device Name: ACTICLOT® Protein S
Regulation Number: 21 CFR 864.7290
Regulation Name: Factor deficiency test
Regulatory Class: Class II
Product Code: GGP
Dated: July 20, 2001
Received: July 27, 2001

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: K012386

Device: ACTICLOT® Protein S

Indications for Use:

The ACTICLOT® Protein S clotting assay is an *in vitro* diagnostic device intended for the quantitative determination of Protein S activity in human plasma.
Protein S activity levels in plasma are known to be low in patients with congenital Protein S deficiencies type-I, type-IIa, and type-IIb, and may also be low in pregnant women, in patients with liver disease and in inflammatory disease in which levels of C4b binding protein are elevated. A decrease in Protein S activity is associated with an increased incidence of thromboembolism.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Josephine Bautista

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K012386