american diagnostica inc.

Revised Section 3

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

AUG 15 2007

Spectrolyse ® PAI-1

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: K063323

Submitted by:

American Diagnostica Inc.
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Stamford, CT 06902
Tel. 203 602-7777
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Contact:

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Summary Prepared:

July 27, 2007

Name of the Device:

Spectrolyse ® PAI-1
Product No. 101201

Classification Name(s):

864.7290	Test, Qualitative And Quantitative Factor Deficiency
GGP	Hematology Reagents, Class II

Predicate Device:

Spectrolyse/pL PAI K922782

Description of the Device

Spectrolyse ® PAI-1 is a two stage colorimetric assay. The first stage involves incubating samples with a known amount of tPA, allowing PAI-1 in the sample to react with tPA. In the second stage, the residual tPA activity converts plasminogen to plasmin, which in turn hydrolyzes a plasmin chromogenic substrate, SPECTROZYME® PL. PAI-1 in the plasma is determined as the difference between the amount of tPA added and the amount of tPA recovered.

Intended Use:
Spectrolyse ® PAI-1, Product # 101201, is intended for the quantitative determination of Plasminogen Activator Inhibitor Type-1 (PAI-1) activity in human plasma. The test is for *in vitro* diagnostic use and is not intended for internal use in humans and animals.

Summary of Substantial Equivalence:

Spectrolyse ® PAI, Product # 101201 is substantially equivalent to the commercially available predicate device Spectrolyse® /pL PAI manufactured by BIOPOOL in performance and intended use.

Summary of Performance Data:

Method Comparison
Two method comparison studies versus the predicate device were performed with two lots of Spectrolyse® PAI-1. The regression statistics in Table 1 indicate a positive correlation between the Spectrolyse® PAI-1 assay and the predicate device.

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

	N	Regression Equation	R	Sy.x (ng/ml)	Sample Range (ng/ml)
Study 1	34	Y=1.0787X+-4.76	0.953	3.31	5.3-37.8
Study 2	34	Y=1.0179X+-3.75	0.955	2.65	5.0-42.3

Precision
Precision studies evaluated intra-assay and inter-assay variability with 3 control samples. In Study #1 control samples were run in replicates of 4 over 20 runs (N=40 per control). In Study #2 control samples were run in replicates of 4 over 5 runs (N= 10 per control). Assay results (IU/mL) were calculated using duplicate determinations. Two lots were evaluated.

Table 2: Precision

	Mean (IU/mL)	Intra-Assay CV%	Inter-Assay CV%
Control 1	10.4	3.6	12.9
Control 2	13.8	3.4	7.5
Control 3	22.2	2.4	3.9

Table 3: Precision

	Mean (IU/mL)	Intra-Assay CV%	Inter-Assay CV%
Control 1	6.7	14.4	10.2
Control 2	14.4	3.5	5.7
Control 3	26.0	2.0	4.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

American Diagnostica, Inc.
C/O David Teicher
500 West Avenue
Stamford, Connecticut 06902

AUG 15 2007

Re: k063323
Trade/Device Name: Spectrolyse® PAI-1, Model 101201
Regulation Number: 21 CFR 864.7290
Regulation Name: Factor Deficiency Test
Regulatory Class: Class II
Product Code: GGP
Dated: July 27, 2007
Received: July 30, 2007

Dear Mr. Teiher:

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Section 2

STATEMENT OF INDICATIONS FOR USE

Applicant: American Diagnostica Inc.

510(k) Number: K063323

Device: Spectrolyse® PAI-1

Indications for Use:

Spectrolyse ® PAI-1 kit, Product # 101201, is intended for the quantitative determination of Plasminogen Activator Inhibitor Type-1 (PAI-1) activity in human plasma. The test is for *in vitro* diagnostic use and is not intended for internal use in humans and animals.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K063323