

K972696

SECTION 3
IL Test™ D-Dimer - 510(k) SUMMARY
(Summary of Safety and Effectiveness)

Submitted by:

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Summary Prepared:

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Name of the device:

IL Test™ D-Dimer

Classification name(s):

864.7320	Fibrinogen/fibrin degradation products assay	Class II
81 DAP	Fibrinogen and Fibrin Split Products, Antigen, Antiserum, Control	

Identification of predicate device(s):

K945642 AGEN's Dimertest® Gold EIA Kit

Description of the device/intended use(s):

IL Test™ D-Dimer permits the quantitative *in vitro* diagnostic determination of D-Dimer in human plasma by turbidimetry. The IL Test™ D-Dimer Latex Reagent is a suspension of latex particles coated with a monoclonal antibody specific for the D-Dimer domain included in fibrin soluble derivatives. When plasma containing D-Dimer is mixed with the D-Dimer Latex Reagent and Reaction Buffer, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of D-Dimer in the sample and is determined by measuring the decrease of the transmitted light caused by the aggregates (turbidimetric immunoassay).

Statement of how the Technological Characteristics of the Device compare to the Predicate device:

IL Test™ D-Dimer is a quantitative D-Dimer test like the predicate Dimertest® Gold EIA Kit and is substantially equivalent in performance, intended use, and safety and effectiveness.

Summary of Performance Data:

In a method comparison study evaluating 105 plasma samples, the correlation (*r*) of IL Test™ D-Dimer to the predicate device was 0.998 on both the ACL 6000 and on the ACL. On the ACL 6000, within precision accessed over multiple runs gave a CV of 4.4% (at a mean of 390 ng/mL), 2.4% (at a mean of 888 ng/mL) and 2.2% (at a mean of 1055 ng/mL). On the ACL Futura, within run precision accessed over multiple runs gave a CV of 6.9% (at a mean of 411 ng/mL), 2.1% (at a mean of 912 ng/mL) and 2.7% (at a mean of 1051 ng/mL).

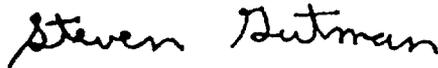
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
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Enclosure

