JUN 0 3 2002

K021257

510(k) Summary of
Safety and Effectiveness

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: **Address:**	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Telephone Number: **Facsimile Number:**	(310) 645-8200 (310) 645-9999
Contact Person:	Edward M. Levine, Ph.D. Director of Clinical Affairs
Date of Preparation:	May 14, 2002
Device Name **Trade:**	ANA line Blot™
Catalog Number:	KALAB1 (20 tests)
Common:	An antinuclear antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum.
Classification:	Class II device, LKJ (21CFR 866.5100)
Manufacturer:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, CA 90045 (The Quality System of Diagnostic Products Corporation is registered to ISO 9001:1994)
Establishment Registration Number	DPC's Registration Number 2017183
Substantially Equivalent Predicate Device:	Helix Diagnostics Enzyme Immunoassay Antinuclear Antibody Screening Test (K954723)

Description of the Device:

The ANA line Blot is a clinical device designed to identify antibodies in human serum, against various cytoplasmic and nuclear antigens. This product is intended strictly for *in vitro* diagnostic use as an aid in the diagnosis of autoimmune diseases.

Intended Use of the Device:

ANA line Blot is an antinuclear antibody screening test designed to identify IgG antibodies in human serum, against the following cytoplasmic and nuclear antigens, collectively in one strip: centromere, dsDNA, histones, Jo-1, Scl-70, SSA (SSA Ro52, SSA Ro60), SSB, Sm (SmB and SmD), RNP (RNP-70, RNP-A and RNP-C), and Ribosomal RNP (RPO). The test is intended as an aid in the diagnosis of autoimmune diseases such as systemic lupus erythematosus (SLE), multiple connective tissue disorders, Sjögren's syndrome, CREST syndrome, scleroderma (progressive systemic sclerosis, PSS), and myositis.

Technology Comparison:

Provided below is a comparison of DPC's ANA line Blot technology versus the Helix Diagnostics Enzyme Immunoassay Antinuclear Antibody Screening Test technology.

ANA line Blot is a line blot technique utilizing purified native and recombinant autoantigens – Centromere, DSDNA, Histones, Jo-1, Scl-70, SSA, SSB, Sm, RNP and Ribosomal RNP – that are immobilized on a nitrocellulose membrane in the form of a line. In addition, a reagent control line and a cutoff control line are also immobilized on the membrane. ANA line Blot strips are incubated with patient serum. Patient IgG binds to autoantigens immobilized on the membrane strip. Alkaline phosphatase-labeled monoclonal anti-human IgG antibodies are then incubated with the nitrocellulose membrane strip. The labeled anti-human IgG antibodies recognize patient IgG that has complexed to the autoantigens. Immune complexes are visualized by a subsequent substrate reaction.

The **Helix Diagnostics Enyzme Immunoassay Antinuclear Antibody Screening Test** is a qualitative immunoassay. Purified antigens (dsDNA, histones, SS-A/Ro, SS-B/La, Sm, SmRNP, Scl-70, Jo-1, centromere and other antigens extracted from the Hep-2 nucleus) are bound to microwells. Antibodies to these antigens, if present in diluted serum, bind in the microwells. Washing of the microwells removes unbound serum antibodies. Horseradish peroxidase (HRP) conjugated anti-human IgG immunologically binds to the bound patient antibodies forming a "conjugate - antibody - antigen" sandwich. Washing of the microwells removes unbound conjugate. An enzyme substrate in the presence of bound conjugate hydrolyzes to form a blue color. The addition of an acid stops the reaction forming a yellow end product. The intensity of the color is measured photometrically at 450nm.

Performance Equivalence:

Diagnostic Products Corporation (DPC) asserts that the ANA line Blot produces substantially equivalent results to other commercially marketed autoimmune disease assays, such as the Helix Diagnostics Enzyme Immunoassay Antinuclear Antibody Screening Test (K954723). Both are designed to identify antibodies in human serum, against various cytoplasmic and nuclear antigens. Each product is intended strictly for *in vitro* diagnostic use as an aid in the diagnosis of autoimmune diseases.

Method Comparison

Two hundred and sixty-nine specimens from apparently healthy subjects and patients with different autoimmune diseases were tested by the ***ANAline Blot*** assay and by a commercially available enzyme immunoassay antinuclear antibody screening test (Kit A). These included 51 specimens from apparently healthy subjects (6 males, 44 females, and 1 unstated), with an average age of 49 years (Range: 6 – 93). Also included were 218 specimens from autoimmune disease patients (32 males, 107 females, and 79 unreported) such as CREST syndrome, systemic lupus erythematosus (SLE), and systemic sclerosis, with an average age of 41 years (Range: 10 – 80). The following results were obtained:

		ANA line Blot	
Helix	Pos	16	193
	Neg	51	9
		Neg	Pos

N	269
Total Agreement	91%
Pos. Agreement	92%
Neg. Agreement	85%

95% Confidence Limits for Positive and Negative Agreements, respectively: 88% - 96%, 73% - 93%.

Conclusion:

The data presented in this summary of safety and effectiveness is the data that the Food and Drug Administration used in granting DPC substantial equivalence for the ANA line Blot.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 0 3 2002

Edward M. Levine, Ph.D.
Director of Clinical Affairs
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045-5597

Re: k021257
Trade/Device Name: ANA line Blot™
Regulation Number: 21 CFR § 866.5100
Regulation Name: Antinuclear Antibody Immunological Test System
Regulatory Class: II
Product Code: LKJ
Dated: April 18, 2002
Received: April 19, 2002

Dear Dr. Levine:

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

510(k) Number (if known): K021257
Device Name: ANA line Blot™

Indications For Use:

ANA line Blot is an antinuclear antibody screening test designed to identify IgG antibodies in human serum, against the following cytoplasmic and nuclear antigens, collectively in one strip: centromere, dsDNA, histones, Jo-1, Scl-70, SSA (SSA Ro52, SSA Ro60), SSB, Sm (SmB and SmD), RNP (RNP-70, RNP-A and RNP-C), and Ribosomal RNP (RPO). The test is intended as an aid in the diagnosis of autoimmune diseases such as systemic lupus erythematosus (SLE), multiple connective tissue disorders, Sjögren's syndrome, CREST syndrome, scleroderma (progressive systemic sclerosis, PSS), and myositis.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Sonjan S. Altaie

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021257

✓ Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)