JUL 23 1999

K992041

immuno concepts

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* 510(k) SUMMARY*
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Date Prepared: July 12, 1999
Contact Person: Eric S. Hoy, Ph.D., SI(ASCP)
Name of Device:

- Trade Name - RELISA® ANA Screening Test System
- Common Name - Antinuclear Antibody Enzyme Immunoassay Test System
- Classification Name - Antinuclear Antibody (21 CFR 866.5100)

Legally marketed device with which this device has been shown to be equivalent:

Enzyme Immunoassay Antinuclear Antibody Screening Test Kit manufactured by Helix Diagnostics, West Sacramento, CA, K954723.

Description:

This is an enzyme immunoassay for the detection of antinuclear antibodies in human serum.

Intended Use:

This is an enzyme immunoassay test system for the detection of antinuclear antibodies in human serum. This test system is to be used as an aid in the detection of antibodies associated with systemic rheumatic disease.

Summary of Technological Characteristics Compared to the Predicate Device:

Technologically, this device is similar to the predicate device with the following exceptions:
a) The predicate device has all 96 microwells sealed in a single pouch. After this pouch is opened, the wells remain stable for only 30 days. The present device has each eight well strip of microwells sealed in an individual pouch, so that unused wells remain in the pouches, and maintain at least 12 months stability.
b) The predicate device uses a cutoff control serum, the present device uses a calibrator serum in the kit.

Description of Laboratory Data That Indicate Substantial Equivalence:

For direct determination of relative sensitivity and specificity, we used the Enzyme Immunoassay Antinuclear Antibody Screening Test Kit manufactured by Helix Diagnostics, West Sacramento, CA, (K954723) as a reference method. The data obtained in this comparison are shown in the following Table.

		Helix Diagnostics Enzyme Immunoassay Antinuclear Antibody Screening Test	
		Positive	**Negative**
Immuno Concepts RELISA® Antinuclear Antibody Test	**Positive**	214	46
	Borderline	12	105
	Negative	8	787

Borderline results were considered positive. These data show an overall agreement of 85.4%

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(916) 363-2649·(800) 251-5115·FAX: (916) 363-2843

The large number of "false positive" samples seen with the Immuno Concepts test was troubling, so we tested all of these sera for antinuclear antibodies using Immuno Concepts HEp-2000® ANA-Ro Test System (K944096 & K972145). Seventy-nine of the "false positive" samples were shown to have clearly discernible ANA patterns with the indirect fluorescent antibody technique and were considered "true positives" for the detection of antinuclear antibodies. Four of the "false negative" samples were shown to be negative by the indirect fluorescent antibody technique and were considered "true negatives" for the detection of antinuclear antibodies. Thus, when the referee method is taken into account, the comparison looks like this:

		Reference Method	
		Positive	**Negative**
Immuno Concepts RELISA® Antinuclear Antibody Test	**Positive**	305	72
	Negative	4	791

These data show an overall agreement of 93.5%

In accordance with 21 CFR 807.92(b)(3), we conclude from these data that the present device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 23 1999

Eric S. Hoy, Ph.D., SI (ASCP)
Chief Scientific Officer
Regulatory Affairs
Immuno Concepts, N.A., Limited
2280 Springlake Road, Suite 106
Dallas, Texas 75234

Re: K992041
Trade Name: RELISA® ANA Screening Test System
Regulatory Class: II
Product Code: LJM
Dated: June 15, 1999
Received: June 17, 1999

Dear Dr. Hoy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 (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): K992041

Device Name: RELISA® ANA Screening Test System

Indications for use:

This is an enzyme immunoassay test system for the detection of antinuclear antibodies in human serum. This test system is to be used as an aid in the detection of antibodies associated with systemic rheumatic disease.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Markus

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

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