

SEP 13 1996



K963275

* 510(k) SUMMARY *

Date Prepared: August 12, 1996
Contact Person: Eric S. Hoy, Ph.D.
Name of Device:

- Trade Name - RELISA® ENA Single Well Screen Antibody Test System
- Common Name - ENA Single Well Screen Antibody Test System
- Classification Name - Extractable Antinuclear Antibody (21 CFR 866.5100)

Legally marketed device with which this device has been shown to be equivalent:
RELISA® ENA Multiparameter Antibody Screening Test System, K935129

Description:

This is an enzyme immunoassay for the detection of antibodies to extractable nuclear antigens Sm, RNP, SS-A/Ro, SS-B/La, Scl-70, or Jo-1 in human serum.

Intended Use:

This test system is for in vitro diagnostic use for the detection of antibodies to nuclear antigens Sm, RNP, SS-A/Ro, SS-B/La, Scl-70, or Jo-1 in human serum. The results from this assay can be used as an aid in the diagnosis of autoimmune diseases.

Summary of Technological Characteristics Compared to the Predicate Device:

This device is identical to the predicate device with the following exceptions:

- a) The predicate device has six different autoantigens coated on individual microwells; the present device has all six autoantigens coated on a single microwell.
- b) The predicate device includes a procedure control well on each strip of microwells, the present device includes 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 Immuno Concepts RELISA® Multiparameter ENA Screening Assay (K935129) as a reference method. The data obtained in this comparison are shown in the following Table.

	Immuno Concepts RELISA® Positive	Multiparameter Borderline	ENA Screening Test Negative
Positive	126	9	5
Borderline	0	2	4
Negative	1	2	394

If we consider borderline results to be positive, these data yield the following statistics: relative sensitivity, 97.9%; relative specificity, 97.8%; and overall agreement, 97.8%

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.