

K974478

FEB - 9 1998



*** 510(k) SUMMARY ***

Date Prepared: November 24, 1997

Contact Person: Eric S. Hoy, Ph.D.

Name of Device:

- Trade Name - Immuno Concepts Antineutrophil Cytoplasmic Antibody Test System with Ethanol Fixed Human Neutrophils
- Common Name - Immuno Concepts ANCA Test System with Ethanol Fixed Human Neutrophils
- Classification Name - Antineutrophil Cytoplasmic Antibody (21 CFR 866.5660)

Legally marketed device with which this device has been shown to be equivalent:
NOVA Lite™ ANCA, INOVA Diagnostics, San Diego, CA, K961340

Description:

This is an indirect fluorescent antibody test for the semi-quantitative detection of antineutrophil cytoplasmic antibody in human serum

Intended Use:

This test system is for in vitro diagnostic use for the detection of antineutrophil cytoplasmic antibody in human serum. This test system is to be used as an aid in the detection of antibodies associated with autoimmune vasculitis, Wegener's granulomatosis, microscopic polyarteritis, and idiopathic crescentic glomerulonephritis.

Summary of Technological Characteristics Compared to the Predicate Device:

Both the predicate device and this device are fluorescent antibody tests for the detection of antineutrophil cytoplasmic antibody in human serum.

Description of Laboratory Data That Indicate Substantial Equivalence:

Serum Samples Obtained from Normal Blood Donors

Serum samples from 497 blood donors (247 males and 250 females) were tested using the subject device and the predicate device. The results of this comparison are shown in the following Table:

	Predicate Device	
	Positive	Negative
Immuno Concepts ANCA	47	23
	124	303

The large number of ANCA positive samples in these otherwise normal individuals was troubling, so we tested all positive sera for antinuclear antibodies (ANA) using Immuno Concepts HEp-2 ANA Test System, and for antibodies to MPO and PR3 using ELISA kits obtained from elias usa, inc. Twenty-two samples were found to have antinuclear antibodies and were considered uninterpretable for ANCA. Excluding these samples, we obtained the following data for the normal blood donor samples:

	Predicate Device	
	Positive	Negative
Immuno Concepts ANCA	41	18
	113	303

Among the remaining discrepant samples, only one was found to be positive for MPO and PR3 antibodies. This sample and the samples that were IFA positive on both the predicate device and the subject device were considered true positives for the comparison of the IFA kits. The remaining samples were considered to be false positives on the respective assays. Thus, when the referee method is taken into account, the comparisons look like this:

		Reference Method	
		Positive	Negative
Immuno Concepts ANCA	Positive	42	17
	Negative	0	416

		Reference Method	
		Positive	Negative
NOVA Lite™ ANCA	Positive	42	112
	Negative	0	321

Serum Samples Previously Determined to be Positive for ANCA by Indirect Immunofluorescence

Serum samples which had been judged to be positive for ANCA using in-house IFA assays were obtained from reference laboratories in the USA, the United Kingdom, and Australia. A total of 383 sera, which we expected to be positive for ANCA, were examined in this part of the study. These samples were tested on the predicate device and the subject device with the following results:

		Predicate Device	
		Positive	Negative
Immuno Concepts ANCA	Positive	283	76
	Negative	11	13

The discrepant samples were tested for MPO and PR3 antibodies by ELISA. When this referee method was taken into account, the comparisons showed the following data:

		Reference Method	
		Positive	Negative
Immuno Concepts ANCA	Positive	338	15*
	Negative	6	18

		Reference Method	
		Positive	Negative
NOVA Lite™ ANCA	Positive	289	5
	Negative	55	28*

* Six samples were atypical pANCA patterns from patients with inflammatory bowel disease, and were excluded from these data.

Combining the data from the normal blood donor population and the expected positive samples, we obtained the following data on the initial comparison of the subject device and the predicate device:

		Predicate Device	
		Positive	Negative
Immuno Concepts ANCA	Positive	324	94
	Negative	124	316

Relative sensitivity : 72.3%
 Relative specificity: 77.1%
 Overall agreement: 74.6%

Taking into account the results of the specific MPO and PR-3 testing, the two tests yield the following data:

		Reference Method	
		Positive	Negative
Immuno Concepts ANCA	Positive	380	32
	Negative	6	434

		Reference Method	
		Positive	Negative
NOVA Lite™ ANCA	Positive	331	117
	Negative	55	349

These data yield the following comparative statistics when all tests are taken into account:

For Immuno Concepts ANCA:	For NOVA Lite™ ANCA:
Relative sensitivity : 98.4%	Relative sensitivity : 85.8%
Relative specificity: 93.1%	Relative specificity: 74.9%
Overall agreement: 95.5%	Overall agreement: 79.8%

Serum Samples From Patients With Known Vasculitides

Samples obtained from 102 patients with clinically characterized vasculitides were tested using the Immuno Concepts ethanol fixed neutrophils. The results of this comparison are shown in the following Table:

Clinical Diagnosis	Number	Positive	Staining Pattern (Ethanol Fixed)
Wegener's granulomatosis	30	26 (86.7%)	all cANCA
Polyarteritis nodosa	12	8 (66.7%)	all pANCA
Microscopic polyarteritis	20	18 (90.0%)	all pANCA
Churg-Strauss Syndrome	3	2 (66.7%)	one pANCA; one both pANCA and cANCA
Immune Complex Crescentic Glomerulonephritis	15	10 (66.7%)	all pANCA
Inflammatory Bowel Disease	22	17 (77.3%)	all atypical pANCA

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.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB - 9 1998

Eric S. Hoy, Ph.D.
Chief Scientific Officer
Immuno Concepts Incorporated
9779 "I" Business Park Drive
Sacramento, California 95827

Re: K974478
Trade Name: Immuno Concepts ANCA Test System with Ethanol
Fixed Human Neutrophils
Regulatory Class: II
Product Code: MOB
Dated: November 24, 1997
Received: November 26, 1997

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 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 requirement, 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.

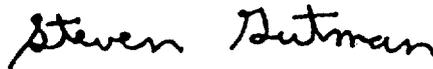
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K974478

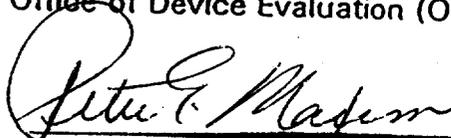
Device Name: Immuno Concepts ANCA Test System with Ethanol fixed Human Neutrophils

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)