

K 97 4463



FEB - 9 1998

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\* 510(k) SUMMARY \*  
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**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 Formalin Fixed Human Neutrophils
- Common Name - Immuno Concepts ANCA Test System with Formalin 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	Positive	5	9
	Negative	37	446

The relatively high number of ANCA positive samples in these otherwise normal individuals was troubling, so we tested all positive sera for antibodies to MPO and PR3 using ELISA kits obtained from elias usa, inc. Among the IFA positive samples, none were found to be positive for MPO or PR3 antibodies. 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	5	9
	Negative	0	483

		Reference Method	
		Positive	Negative
NOVA Lite™ ANCA	Positive	5	37
	Negative	0	455

**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	250	43
	Negative	8	82

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	288	4
	Negative	5	86

  

		Reference Method	
		Positive	Negative
NOVA Lite™ ANCA	Positive	254	3
	Negative	39	87

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	255	52
	Negative	45	528

Relative sensitivity : 85%  
 Relative specificity: 91%  
 Overall agreement: 89%

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	293	13
	Negative	5	569
NOVA Lite™ ANCA	Positive	259	40
	Negative	39	542

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

For Immuno Concepts ANCA:

Relative sensitivity : 98.3%

Relative specificity: 97.7%

Overall agreement: 98.0%

For NOVA Lite™ ANCA:

Relative sensitivity : 86.9%

Relative specificity: 93.1%

Overall agreement: 91.0%

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

Public Health Service

Food and Drug Administration  
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Rockville MD 20850

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

FEB -9 1998

Re: K974463  
Trade Name: Immuno Concepts ANCA Test System with Formalin  
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.

Page 2

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): K974463

Device Name: Immuno Concepts ANCA Test System with Formalin Fixed Human Neutrophils

Indications For Use:

This is an in vitro diagnostic test system for the detection and semi-quantitation of antineutrophil cytoplasmic antibodies 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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Peter E. Madson*

(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)