

OCT 16 1998

Nichols Institute Diagnostics
Advantage™ Anti-TPO
510(k) Notification

11.0 510(k) SUMMARY *K982866*

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: not known

1. Name of Submitter, Contact Person and Date Summary Prepared:

Nichols Institute Diagnostics
33051 Calle Aviator
San Juan Capistrano, CA 92675-4703
Phone: 949-240-5260
Fax: 949-240-5313

Contact Person: Jimmy Wong
Date Prepared: July 31, 1998

2. Device Name

Trade/Proprietary Name: Nichols Advantage™ Chemiluminescence Thyroid Peroxidase Autoantibodies Immunoassay

Common/Usual Name: Anti-TPO Assay

Classification Name: Thyroid, Autoantibody Immunological Test System

3. Predicate Device:

We claim substantial equivalence to the Nichols Institute Diagnostics Chemiluminescence Thyroid Peroxidase Autoantibodies Immunoassay (K931311, Cleared 5/14/93).

4. Device Description:

The Nichols Advantage™ Anti-TPO is a two-site chemiluminescence assay for use with the Nichols Advantage™ Specialty System

5. Intended Use

The Nichols Advantage™ Chemiluminescence Thyroid Peroxidase Autoantibodies Immunoassay is intended for use on the Nichols Advantage™ Specialty System for the quantitative determination of Thyroid Peroxidase Autoantibodies (TPOAb) in human serum as an aid in the diagnosis and assessment of patients with autoimmune thyroid disease.

6. Comparison to predicate device:

The Nichols Advantage™ Anti-TPO is substantially equivalent to other products in commercial distribution for similar use. Most notably, it is substantially equivalent to the NID Chemi Anti-TPO Immunoassay kit.

The following tables compare the Nichols Advantage Anti-TPO with the predicate device, NID Chemi Anti-TPO Immunoassay kit.

Similarities:

- Intended Use: For the quantitative determination of Anti-TPO in human serum.
- Both assays use recombinant TPO to bind specific Anti-TPO autoantibodies.
- Both assays use human serum for the test sample.
- The sensitivity of both assays is sufficient to measure Anti-TPO autoantibody levels found in patients with autoimmune disease.

Differences:

Feature	Nichols Advantage™ Anti-TPO	Nichols Institute Diagnostics Chemiluminescence Anti-TPO
Sample Size	15 uL of sample diluted with 435 uL of Assay Diluent (1:30 dilution). 65 uL of diluted sample assayed.	50 uL of sample diluted with 1000 uL of Assay Diluent (1:21 dilution). 100 uL of diluted sample assayed.
Calibration	Two point calibration every two weeks (maximum) of stored working calibration curve; or when controls out of range.	Full calibration curve with every run.
Solid Phase	Streptavidin-coated magnetic particles. Streptavidin-biotin separation technology.	6 mm bead
Incubation	30 minutes at 37°C	2 hours at room temperature
Sensitivity	0.5 IU/mL in serum	0.2 IU/mL in serum

Performance Characteristics:

FEATURE	Nichols Advantage™ Chemiluminescence Anti-TPO			Nichols Institute Diagnostics Chemiluminescence Anti-TPO		
	Mean (IU/mL)	n	%CV	Mean (IU/mL)	n	%CV
Intra-Assay	3.4	20	5.4	2.4	21	10.7
	8.6	20	5.0	77	22	7.5
	52.9	20	3.9			
Inter-Assay	Mean (IU/mL)	n	%CV	Mean (IU/mL)	n	%CV
	3.4	20	14.3	9.6	23	9.7
	8.5	20	9.6	30	10	9.1
	54.0	20	9.1			
Recovery	94 - 107%			92 - 113%		
Parallelism	88 - 117%			Not Done		
High Dose Hook Effect	> 4,000 IU/mL			Not Done		
Specificity and Cross-Reactivity:						
Anti-Thyroglobulin	Undetectable			Not Done		
Thyroglobulin	Undetectable			Not Done		
Method Comparison	Preliminary Reference Range: Normal < 2.0 IU/mL					
Range of Results	0.02 - 1548			0.00 - 1783		
Binomial Test Statistic	P(X) = 0.0611					
Relative Sensitivity	94.1%					
Relative Specificity	94.2%					
Agreement	94.1%					



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 16 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Jimmy Wong
Manager, Clinical and
Technical Affairs
Nichols Institute Diagnostics
33051 Calle Aviador
San Juan Capistrano, California 92675-4703

Re: K982866
Trade Name: Nichols Advantage™ Chemiluminescence Thyroid
Peroxidase Autoantibodies Immunoassay
Regulatory Class: II
Product Code: JZO
Dated: July 31, 1998
Received: August 14, 1998

Dear Mr. Wong:

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.

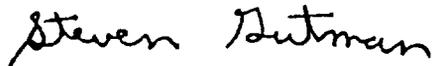
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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 I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 INDICATIONS FOR USE STATEMENT

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K982866

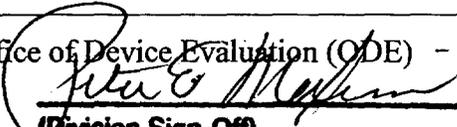
Device Name: Nichols Advantage™ Chemiluminescence Thyroid Peroxidase Autoantibodies
Immunoassay

Indications For Use:

The Nichols Advantage™ Chemiluminescence Thyroid Peroxidase Autoantibodies Immunoassay is intended for use on the Nichols Advantage™ Specialty System for the quantitative determination of Thyroid Peroxidase Autoantibodies (TPOAb) in human serum as an aid in the diagnosis and assessment of patients with autoimmune thyroid disease.

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

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)