

JAN 26 1999

510(k) SUMMARY

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: K983992

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

Nichols Institute Diagnostics
33051 Calle Aviator
San Juan Capistrano, CA 92675
Phone: 714-240-52690
Fax: 714-240-5313

Contact Person: Jimmy Wong
Date Prepared: January 21, 1999

2. Device Name

Trade/Proprietary Name: Nichols Advantage® Chemiluminescence Thyroglobulin Autoantibodies Immunoassay

Common/Usual Name: Anti-Tg Assay

Classification Name: Thyroid, Autoantibody Immunological Test System

3. Predicate Device:

We claim substantial equivalence to the Nichols Institute Diagnostics Chemiluminescence Thyroglobulin Autoantibodies assay.

4. Device Description:

The Nichols Advantage® TgAb chemiluminescence immunoassay is a two-site immunometric method based on binding anti-thyroglobulin antibodies in human serum to human thyroglobulin (Tg). Total duration of assay is 31.5 minutes at 37°C.

5. Intended Use

The Nichols Advantage® Chemiluminescence Thyroglobulin Autoantibodies Immunoassay is designed for use with the Nichols Advantage® Specialty System for the quantitative determination of thyroglobulin autoantibodies (TgAb) in human serum. This assay is intended to aid in the diagnosis and assessment of patients with autoimmune thyroid disease.

6. Comparison to predicate device:

The Nichols Advantage® Thyroglobulin Autoantibodies Immunoassay is substantially equivalent to other products in commercial distribution for similar use. Most notably it is substantially equivalent to the Nichols Institute Diagnostics Chemiluminescence Thyroglobulin Autoantibodies assay.

The following tables compare the new device with the predicate device.

Similarities:

- Intended Use: For the quantitative determination of TgAb in human sera.
- Both assays use highly purified thyroglobulin of human origin.
- Both assays use human serum for the test sample.
- The sensitivity of both assays is sufficient to measure TgAb levels found in patients with autoimmune thyroid disease.
- Pooled sera with high concentrations of TgAb are used as standards in the both assays. The standard is calibrated to WHO 1st IRP 65/93.
- Both methods are based on acridinium conjugated Tg and biotin coupled Tg to produce a sandwich complex with the patient's TgAb.

Differences:

Feature	Nichols Advantage TgAb	Predicate Device
Sample Size	20 uL 1:15 dilution with assay diluent. 60 uL of the diluted sample is assayed.	100 uL 1:10 dilution with assay diluent. 100 uL of the diluted sample is assayed.
Calibration	Two-point calibration stable for one week from working calibration curve, or when controls are out of range.	Full calibration curve with every run.
Assay Set-up	Automated	Manual
Solid Phase	Streptavidin coated magnetic particles. Streptavidin-biotin separation technology.	6 mm bead
Incubation	31.5 minutes at 37C	2 hours at room temperature using a rotator.
Reportable Range	Approx. 0.3-90 IU/mL	Approx. 0.2-60 IU/mL.

Performance Characteristics:

Feature	Nichols Advantage TgAb			Predicate Device		
	Mean (UI/mL)	N	%CV	Mean (UI/mL)	N	%CV
Intra-Assay	3.6	20	7.2	1.9	20	8.7
	13.8	20	6.1	41	20	5.9
	60.2	20	5.8			
Inter-Assay	4.0	20	12.9	3.1	15	14.2
	13.7	20	6.1	36	22	7.7
	55.0	20	6.8			
Recovery	94 - 113%			83 - 111%		
High Dose Hook	4,000 IU/mL			Not Done		
Specificity and Crossreactivity						
Recombinant hTPO @ 200 mg/L	95% recovery			Not Done		
TPO Ab @ 2000 IU/mL	91% recovery			Not Done		
Method Comparison:						
Range of results	Undetectable to 2,089 IU/mL			Undetectable to 2,190 IU/mL		
Binomial Test Statistic	P(X) = 0.25					
Relative Sensitivity	100%					
Relative Specificity	98.3%					
Agreement	98.6%					
Reference Range:	Up to 1 IU/mL			Up to 2 IU/mL		



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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

Re: K983992
Trade Name: Nichols Advantage® Chemiluminescence Thyroglobulin Autoantibodies
Immunoassay
Regulatory Class: II
Product Code: JZO
Dated: November 6, 1998
Received: November 9, 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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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 I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K983992

Device Name: Nichols Advantage® Chemiluminescence Thyroglobulin Autoantibodies
Immunoassay

Indications For Use:

The Nichols Advantage® Chemiluminescence Thyroglobulin Autoantibodies Immunoassay is designed for use with the Nichols Advantage® Specialty System for the quantitative determination of thyroglobulin autoantibodies (TgAb) in human serum. This assay is intended to 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

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Prescription Use

(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)