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: ~~K965031~~ K980716 APR - 3 1998

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

Nichols Institute Diagnostics
33051 Calle Aviador
San Juan Capistrano, California 92675
Phone: 714-240-5260
Fax: 714-240-5313

Contact Person: Jimmy Wong
Date Prepared: January 5, 1998

2. ***Device Name:***

Trade/Proprietary Name:	Nichols Advantage™ Chemiluminescence Prostate Specific Antigen Assay
Common/Usual Name:	Chemiluminescence assay for the determination of prostate-specific antigen (PSA).
Classification Name:	System, Test, Prostate Specific Antigen

3. ***Predicate Device:***

We claim substantial equivalence to the Hybritech Tandem®-R PSA

4. ***Device Description:***

The Nichols Advantage™ PSA is a two-site chemiluminescence assay. Total duration of assay is 30 minutes at 37^0C.

1st Incubation: 20 minutes at 37^0C. Sample or control or calibrator (20uL), biotinylated monoclonal PSA specific antibody (80uL), and acridinium labeled rabbit specific antibody (50uL) react to form a sandwich complex.

2nd Incubation: 10 minutes at 37^0C. Assay buffer (50uL) and streptavidin coated magnetic particles (25uL) are added to the reaction mixture. After the 10 minute incubation, the sandwich complex is bound to the solid phase via the interaction of biotin and streptavidin.

The reaction mixture is aspirated from the reaction well after the streptavidin magnetic particles are magnetically captured onto the surface of the reaction well wall. The magnetic particles are washed three times with system wash buffer.

Acridinium esters emit light upon treatment with hydrogen peroxide and an alkaline solution. The Trigger 1 solution contains hydrogen peroxide in dilute acid and Trigger 2 solution contains dilute sodium hydroxide. The system automatically injects Trigger 1 and 2 into the reaction well which oxidize the acridinium ester. The oxidized product is in an excited state. The subsequent return to ground state results in the emission of light which is quantified in 2 seconds, and is expressed in relative light units (RLU) by the integrated system luminometer.

The amount of bound labeled antibody in RLU's is directly proportional to the concentration of PSA in the sample. Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent bar codes.

5. ***Intended Use:***

Intended for use with the Nichols Advantage Specialty System for the quantitative determination of prostate specific antigen (PSA) in human serum and is to be used as an adjunct in the management of patients with prostate cancer.

6. ***Comparison to predicate device:***

The Nichols Advantage PSA is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Hybritech Tandem®-R PSA.

The following tables compare the Nichols Advantage™ PSA with the predicate device, Hybritech Tandem®-R PSA.

Similarities:

- Intended Use: For the quantitative measurement of prostate specific antigen (PSA) and is to be use as an aid in the management of patients with prostate cancer.
- Both assays use mouse monoclonal antibodies to bind PSA molecules.
- Both assays are based on two-site immunometric assay technique (sandwich assays).
- Both assays use human serum for the test specimen.
- The sensitivity of the two assays are similar (0.1 ng/mL).

Differences:

Feature:	Nichols Advantage™ PSA	Hybritech Tandem®-R PSA
Sample Size	20uL	50uL
Detection Method	Acridinium labeled antibody. RLU is the signal.	^{125}I labeled antibody Gamma radiation in CPM is the signal.
Instrument Requirements	Nichols Advantage Specialty System	Gamma Photon System or gamma counter.
Calibration:	Full calibration curve every 2 weeks with 2 point calibration every 4 hours.	Full calibration curve with every run.
Standardization	Stamey/Stanford Reference Standard (90% PSA-ACT + 10% free PSA)	Different reference material.
Solid Phase:	Streptavidin magnetic particles. Streptavidin-biotin separation technology.	Coated beads with anti-PSA monoclonal antibody.
Reportable Range	0-30 ng/mL	0-100 ng/mL

Performance Characteristics:

Feature:	Nichols Advantage™ PSA			Hybritech Tandem®-R PSA		
Precision:						
	Intra-Assay:			Intra-Assay:		
Level	Pool 1	Pool 2	Pool 3	1	2	3
N	20	20	20	40	40	40
Mean (ng/mL)	0.6	3.9	23.6	5.25	26.8	78.9
%CV	6.1	2.3	2.7	4.4	4.8	4.3
	Inter-Assay:			Inter-Assay:		
Level	Pool 4	Pool 5	Pool 6	1	2	3
N	20	20	20	40	40	40
Mean (ng/mL)	0.7	4.2	27.7	5.2	27.3	79.6
%CV	9.8	3.6	9.1	5.4	4.2	2.4
Sensitivity	0.1 ng/mL			0.1 ng/mL		
High Dose Hook	no hook effect up to 5,000 ng/mL			no hook effect up to 5,000 ng/mL		
Recovery	93-106%			92-95%		
Parallelism	89-108%			not available		
Interfering Subtances:	No interference up to:			No interference up to:		
hemoglobin	800 mg/dL			200 mg/dl		
bilirubin	25 mg/dL			25 mg/dL		
lipemia(triglycerides)	2325 mg/dL			2320 mg/dL		
PAP	1,000 ng/mL			1,000 ng/mL		
Method Comparison	versus Hybritech Tandem-R PSA					
	n=183 split samples					
	Range of values 0.1 to 24.6 ng/mL (Hybritech)					
	Range of values 0.1 to 22.3 ng/mL (Nichols)					
	y = 0.974x + 0.25 (Deming linear regression)					
	95% confidence of the slope: 0.906 - 1.042					
	95% confidence of the intercept: -0.34 to 0.84					
	R = 0.885					

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Nichols Institute Diagnostics
c/o Ms. Cindy Martin
Regulatory Consultant
1711 North Bush Street
Santa Ana, California 92706

APR - 3 1998

Re: K980716
Trade Name: Nichols Institute Diagnostics ADVANTAGE™ Chemiluminescence Prostate Specific Antigen (PSA) Immunoassay
Regulatory Class: II
Product Code: LTJ
Dated: January 5, 1998
Received: January 7, 1998

Dear Ms. Martin:

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.

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 Gutman

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): K980716 K965031

Device Name: Nichols Advantage™ Chemiluminescence Assay Prostate Specific Antigen

Indications For Use:

Intended for use with the Nichols Advantage Specialty System for the quantitative determination of prostate specific antigen (PSA) in human serum and is to be used as an adjunct in the management of patients with prostate cancer.

Peter E. Maples

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K980716

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)