FEB 2 1999

11.0 510(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: ~~not known~~ K984186

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

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

Contact Person: Jimmy Wong
Date Prepared: November 20, 1998

2. Device Name

Trade/Proprietary Name:	Nichols Advantage® Chemiluminescence Ferritin Immunoassay
Common/Usual Name:	Ferritin Assay
Classification Name:	Ferritin Immunological Test System

3. Predicate Device:

We claim substantial equivalence to the Chiron Diagnostics ACS:*180*® Automated Chemiluminescence System Ferritin +C Assay (K905770, Cleared March 12, 1991).

4. Device Description:

The Nichols Advantage® Ferritin Assay is a two-site chemiluminescence assay for use with the Nichols Advantage® Specialty System

5. Intended Use

The Nichols Advantage® Chemiluminescence Ferritin Immunoassay is intended for use on the Nichols Advantage® Specialty System for the quantitative determination of ferritin in human serum or plasma.

6. Comparison to predicate device:

The Nichols Advantage® Ferritin Assay is substantially equivalent to other products in commercial distribution for similar use. Most notably, it is substantially equivalent to the Chiron Diagnostics ACS:*180*® Ferritin Immunoassay.

The following tables compare the Nichols Advantage Ferritin Assay with the predicate device, Chiron Diagnostics ACS:*180* Ferritin Immunoassay .

Similarities:

- Intended Use: For the quantitative determination of ferritin in human serum or plasma (Nichols Advantage Ferritin Assay); in serum (Chiron Diagnostics ACS:180 Ferritin Immunoassay).
- Both assays use specific antibodies to bind ferritin.
- Both assays use human serum for the test sample.
- Both assays use chemiluminometric technology based on acridinium esters.
- The sensitivity of both assays is sufficient to measure ferritin levels found in normal, iron deficient and iron overload patients.

Differences:

Feature	Nichols Advantage® Ferritin	ACS:*180*® Automated Chemiluminescence System Ferritin +C Assay
Sample Size	150 microliters	25 microliters
Calibration	Two point calibration every two weeks (maximum) of stored working calibration curve; or when controls out of range.	Two point calibration every 15 days of stored working calibration curve; or when controls out of range.
Solid Phase	Streptavidin-coated magnetic particles. Streptavidin-biotin separation technology.	Mouse monoclonal anti-ferritin antibodies covalently coupled to paramagnetic particles. Antibody sandwich-formation separation technology.
Incubation	30 minutes at 37°C	7.5 minutes at 37°C
Sensitivity	2 ng/mL in serum or plasma	0.5 ng/mL in serum

Performance Characteristics:

FEATURE	Nichols Advantage® Chemiluminescence Ferritin			Chiron Diagnostics ACS:*180*® Ferritin +C Assay		
Intra-Assay	Mean (ng/mL)	n	%CV	Mean (ng/mL)	n	%CV
	16	20	4.6	13	24	2.8
	48	20	3.9	55	24	2.8
	159	20	4.4	163	24	2.7
	437	20	4.9	360	24	3.6
Inter-Assay	Mean (ng/mL)	n	%CV	Mean (ng/mL)	n	%CV
	19	20	12.2	13	8	5.0
	47	20	7.2	55	8	6.1
	153	20	6.3	163	8	4.9
	372	20	5.9	360	8	5.1
Recovery	94 – 104			93 – 112		
Parallelism	99 - 114			92 – 112		
High Dose Hook Effect	Greater than 16,000 ng/mL			80,000 ng/mL		
Specificity and Cross-Reactivity:						
Spleen Ferritin	100%			Not Determined		
Liver Ferritin	100%			106%		
Method Comparison						
Range of Results	2.3 ng/mL to 608 ng/mL			7.0 ng/mL to 663 ng/mL		
Linear Regression Equation	y = 0.94x – 4.7 ng/mL					
Correlation Coefficient (r)	0.98					

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 1999

Jimmy Wong
Manager, Clinical and Technical Affairs
NICHOLS INSTITUTE DIAGNOSTICS
33051 Calle Aviador
San Juan Capistrano, CA 92675-4703

Re: K984186
Trade Name: Nichols Advantage® Chemiluminescence Ferritin Immunoassay
Regulatory Class: II
Product Code: DBF
Dated: November 20, 1998
Received: November 23, 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.

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 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): K984186

Device Name: Nichols Advantage® Chemiluminescence Ferritin Immunoassay

Indications For Use:

The Nichols Advantage® Chemiluminescence Ferritin Immunoassay is designed for use with the Nichols Advantage® Specialty System for the quantitative determination of ferritin in human serum or plasma. This assay is intended to aid in the diagnosis of iron deficiency anemia and iron overload.

Peter E Mayers

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984186

(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)