K992188

DEC - 6 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

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: James A. Rybski, Ph.D.
Date Prepared: June 18, 1999

2. Device Name:

Trade/Proprietary Name:	Nichols Advantage® Chemiluminescence Soluble Transferin Receptor Immunoassay
Common/Usual Name:	Soluble Transferrin Receptor Assay
Classification Name:	Soluble Transferrin Receptor Immunological Test System

3. Predicate Device:

We claim substantial equivalence to the R&D Systems, Inc. Quantikine™ IVD™ Human Soluble Transferrin Receptor Immunoassay (K970718, Cleared May 27, 1997).

4. Device Description:

The Nichols Advantage® Soluble Transferrin Receptor Assay is a two-site chemiluminescence assay for use with the Nichols Advantage® Specialty System.

5. Intended Use:

The Nichols Advantage® Chemiluminescence Soluble Transferrin Receptor Immunoassay is intended for use on the Nichols Advantage® Specialty System for the quantitative determination of Soluble Transferrin Receptor in human serum, EDTA and Heparin plasma as an adjunct in the diagnosis of Iron Deficiency Anaemia and for the differential diagnosis of Iron Deficiency Anaemia and Anaemia of Chronic Disease.

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 R&D Systems, Inc. Quantikine™ IVD™ Human Soluble Transferrin Receptor Immunoassay.

The following tables compare the Nichols Advantage Ferritin Assay with the predicate device, R&D Systems, Inc. Quantikine™ IVD™ Human Soluble Transferrin Receptor Immunoassay.

Similarities:

- Intended Use: For the quantitative determination of sTfR in human serum or plasma.
- Both assays use specific antibodies to bind sTfR.
- Both assays use human serum for the test sample.
- Both assays rely upon a sandwich formation by mouse monoclonal antibodies to specifically detect sTfR.
- The sensitivity of both assays is sufficient to measure sTfR levels found in normal, iron deficient and iron overload patients.

Differences:

Feature	Nichols Advantage® Soluble Transferrin Receptor Assay	Quantikine™ IVD™ Human Soluble Transferrin Receptor Immunoassay
Sample Size	60 microliters	20 microliters
Calibration	Two point calibration every two weeks (maximum) of stored working calibration curve; or when controls out of range.	Five point standard curve run with each assay.
Solid Phase	Streptavidin-coated magnetic particles. Streptavidin-biotin separation technology.	Mouse monoclonal anti-sTfR antibodies adsorbed to microtiter plate wells. Antibody sandwich-formation separation technology.
Incubation	One Incubation: Total of 30 minutes at 37°C	Three Incubations: Total of 2 hr 30 min at room temperature (18-25°C)
Sensitivity	0.1 nmol/L	Less than 0.5 nmol/L

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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James A. Rybski, Ph.D.
Manager, Research and Development
Nichols Institute Diagnostics
33051 Calle Aviador
San Juan Capistrano, California 92675-4703

Re: K992188
Trade Name: Nichols Advantage® Chemiluminescence Soluble Transferrin Receptor *Immunoassay*
Regulatory Class: II
Product Code: JNM
Dated: September 22, 1999
Received: September 27, 1999

Dear Dr. Rybski:

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 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

4.0 INDICATIONS FOR USE STATEMENT

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510(k) Number (if known): K992188

Device Name: Nichols Advantage® Chemiluminescence Soluble Transferrin Receptor Immunoassay

Indications For Use: The Nichols Advantage® Chemiluminescence Soluble Transferrin Receptor Immunoassay is intended for use on the Nichols Advantage® Specialty System for the quantitative determination of Soluble Transferrin Receptor in human serum, EDTA and Heparin plasma as an adjunct in the diagnosis of Iron Deficiency Anaemia and for the differential diagnosis of Iron Deficiency Anaemia and Anaemia of Chronic 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 K992188

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)