K984520

FEB 5 1999

510(k) SAFETY AND EFFECTIVENESS SUMMARY

TRADE NAME: Nichols Advantage® Chemiluminescence Cortisol Immunoassay

COMMON NAME: Cortisol

CLASSIFICATION NAME: Cortisol
(21 CFR 862.1205)

The Nichols Advantage® Chemiluminescence Cortisol Immunoassay (hereinafter referred to as the **Assay)** is a Chemilumeniscence assay intended for use with the Nichols Advantage® Specialty System.

INTENDED USE

The **Assay** is intended for the quantitative determination of cortisol concentration in human serum, EDTA plasma, and urine. Measurements of cortisol are used in the diagnosis and treatment of disorders of the adrenal gland.

SUBSTANTIAL EQUIVALENECE

The **Assay** is identical to the Nichols Advantage® Chemiluminescence Cortisol Assay (K962208 cleared 4/8/97) in its intended use; the use of human serum and EDTA plasma with the added intended use of urine, and sensitivity which is sufficient to measure Cortisol found in patients with disorders of the adrenal gland. Studies were performed to show the reproducibility, recovery, extraction efficiency, parallelism, effect of potential interferents in urine, and the expected values in normal individuals. The method we use to extract cortisol from urine is accepted and recognized in the literature. The inter-assay precision estimates of 8.6-10.3% CV are typical for an assay that includes a pre-assay organic solvent extraction step. When urine was analytically spiked with known amounts of cortisol, the mean extraction recovery was 102% indicating that the method to extract cortisol from urine is efficient, complete and reproducible. When various quantities of a high and low cortisol sample were mixed, the analytical recovery across the ranges studied showed recoveries of 98 ± 5% (mean ± SD). When urine was diluted after extraction, the linearity/recovery was 99 ± 9% (mean ± SD) across the ranges studied. Potential interference due to protein, urea, creatinine, glucose and sodium chloride were studied, and the data show no observed interference at the pathological concentrations studied. All these studies document the performance characteristics of measuring urine cortisol by this assay.

Submitted By: Jimmy Wong
Manager, Clinical and Technical Affairs
Nichols Institute Diagnostics
33051 Calle Aviador
San Juan Capistrano, CA 92675-4703
(949) 240-5260

Contact Person: Jimmy Wong

Date: December 15, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 5 1999

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

Re: K984520
Trade Name: Nichols Advantage® Chemiluminescence Cortisol Immunoassay
Regulatory Class: II
Product Code: CGR
Dated: December 15, 1998
Received: December 21, 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

K984520

510(k) NUMBER (If Known): ~~K962208 (Cleared 4/8/99)~~

DEVICE NAME: **Nichols Advantage® Chemiluminescence Cortisol Immunoassay**

INDICATIONS FOR USE:

The Nichols Advantage® Chemiluminescence Cortisol Immunoassay is intended for use with the Nichols Advantage® Specialty System for the quantitative determination of cortisol concentration in human serum, EDTA plasma, and urine. Measurements of cortisol are used in the diagnosis and treatment of disorders of the adrenal gland.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984520

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21CFR 801.109) (Optional Format 1-2-96)