K033302

JAN 2 6 2004

11.0 Special 510k Summary

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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

Nichols Institute Diagnostics
1311 Calle Batido
San Clemente, CA 92673
Phone: 949-940-7260
FAX: 949-940-7313
Contact Person: Jimmy Wong, Manager of Clinical and Technical Affairs
Date Prepared: Jan. 23, 2004

2. **Device Name:**
   Trade/Proprietary Name: Nichols Advantage® Bio-Intact PTH (1-84)
   Common Name: Parathyroid hormone immunoassay
   Classification Name: Radioimmunoassay, Parathyroid Hormone
3. **Classification:** Class II
   Regulation Number: 862.1545
   Product Code: CEW, Clinical Chemistry
4. **Predicate Device:** Nichols Advantage Bio-Intact PTH (1-84) K013992
5. **Device Description:** The Nichols Advantage Aldosterone assay contains sufficient reagents for 100 tests. The assay is a direct chemiluminescence immunometric assay for quantifying PTH in human serum or plasma.
6. **Intended Use:** The Nichols Advantage® Bio-Intact PTH (1-84) immunometric assay is intended for use with the Nichols Advantage® Specialty System to measure the levels of parathyroid hormone in serum and EDTA plasma. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) and hypocalcemia (abnormally low levels of calcium in the blood) resulting from disorders of calcium metabolism. Assay results should be used in conjunction with other clinical data to assist the clinician in making individual patient management decisions.

7. **Conclusions:** The Nichols Advantage Bio-Intact PTH (1-84) assay (FDA 510k K013992 previously cleared on Dec. 13, 2001) was updated to include new information and labeling.

   Changes to the Expected Values section were made in the labeling. A new reference range study was performed, and the results of that study were included in the new labeling. Clinicians, and laboratory users of the Nichols Bio-Intact PTH (1-84) assay are being provided the new information so that they can make informed decisions on how to conduct their own reference range studies, and how such information can be used to interpret PTH results. New information is the biological covariates that can affect calcium metabolism and their associated effects on parathyroid hormone levels, and literature references that pertain to this topic.

   The Special 510(k) includes new data on the clinical performance of the test performed on patient samples with known clinical disorders of calcium metabolism. Serum calcium and PTH testing was performed on n=63 patients with surgically confirmed primary hyperparathyroidism, n=7 patients with hypoparathyroidism, n=3 patients with hypercalcemia due to malignancy, and n=276 normal individuals. By plotting the serum calcium (x-axis) versus the Bio-Intact PTH (y-axis) a clinical scattergram was created. The scattergram serves to help in the differential diagnosis of hypercalcemia and hypocalcemia when both Bio-Intact PTH (1-84) and calcium testing are performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 6 2004

Mr. Jimmy Wong
Manager, Clinical and Technical Affairs
Nichols Institute Diagnostics
1311 Calle Batido
San Clemente, CA 92673

Re: k033302
Trade/Device Name: Nichols Advantage Bio-Intact PTH (1-84)
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid hormone test system
Regulatory Class: Class II
Product Code: CEW
Dated: December 19, 2003
Received: December 31, 2003

Dear Mr. Wong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

3.0 Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number: K033302

Device Name: Nichols Advantage Bio-Intact PTH (1-84)

Indications for Use Statement: The Nichols Advantage® Bio-Intact PTH (1-84) immunometric assay is intended for use with the Nichols Advantage® Specialty System to measure the levels of parathyroid hormone in serum and EDTA plasma. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) and hypocalcemia (abnormally low levels of calcium in the blood) resulting from disorders of calcium metabolism. Assay results should be used in conjunction with other clinical data to assist the clinician in making individual patient management decisions.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **Over –The-Counter Use**

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

Carol C Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033302 **SPECIAL**