12.0 510(k) SUMMARY

K033727

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of CFR 807.92.

510(k) Number: Not Known

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

Nichols Institute Diagnostics
1311 Calle Batido
San Clemente, CA 92673
Phone: 949-940-7417
Fax: 949-940-7440

Contact Person: Robert L. Schmidt
Date Prepared: November 25, 2003

2. **Device Name**

Trade/Proprietary Name:	Nichols Advantage® Bio-Intact PTH (1-84) Immunoassay
Common/Usual Name:	Bio-Intact PTH (1-84) Assay
Classification Name:	Radioimmunoassay, Parathyroid Hormone

3. **Predicate Device:**

The device that is the subject of this submission is substantially equivalent to the Nichols Advantage® Bio-Intact (1-84) PTH Immunoassay (K013992; Cleared 12/31/01). This 510(k) is for labeling changes to the predicate device.

4. **Device Description:**

The Bio-Intact PTH (1-84) Assay is a two-site chemiluminescence assay for use with the Nichols Advantage® Specialty System.

5. **Intended Use**

The Nichols Advantage® Bio-Intact PTH (1-84) immunoassay is intended for use with the Nichols Advantage® Specialty System to measure the levels of parathyroid hormone in serum, EDTA plasma and heparinized 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. Measurements of parathyroid hormone levels with the Bio-Intact PTH (1-84) Immunoassay are also used as an aid in monitoring therapeutic intervention of secondary hyperparathyroidism that frequently occurs in chronic kidney disease. Assay results should be

used in conjunction with other clinical data to assist the clinician in making individual patient management decisions.

6. Comparison to predicate device:

The Bio-Intact PTH (1-84) Assay is substantially equivalent to the Nichols Advantage Bio-Intact PTH(1-84) Immunoassay previously submitted as K013992. The following tables compare the Bio-Intact PTH (1-84) Assay (modified) with the predicate device, the Nichols Advantage Bio-Intact PTH (1-84) Immunoassay (K013992).

Similarities:

- Intended Use: For the quantitative determination of intact PTH in human serum or EDTA plasma.
- Both assays use specific antibodies to bind intact PTH.
- Both assays can use human serum or EDTA plasma for the test sample.
- Both assays use chemiluminometric technology based on acridinium esters.
- Both assays use 150 microliters of sample.
- Both assays use two point calibration every two weeks (maximum) of stored working calibration curve; or when controls out of range.
- Both assays use Streptavidin-coated magnetic particles and streptavidin-biotin separation technology.
- Both assays' total incubation period is 30 minutes at 37°C.
- The sensitivity of both assays is 1.5 pg/mL. (analytical) and 4.0 pg/mL (functional).
- The throughput is the same for both assays at 180 test/hour.
- The cross reactives are the same between assays.
- The recovery is the same between assays.
- The parallelism is the same between assays.
- The high dose hook effect is the same between assays.

Differences:

Intended Use: The Nichols Advantage® Bio-Intact PTH (1-84) Immunoassay is intended for use with the Nichols Advantage® Specialty System to measure the levels of parathyroid hormone in serum, EDTA plasma and heparinized 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. Measurements of parathyroid hormone levels with the Bio-Intact PTH (1-84) Immunoassay are also used as an aid in monitoring therapeutic intervention of secondary hyperparathyroidism that frequently occurs in chronic kidney disease. Assay results should be used in conjunction with other clinical data to assist the clinician in making individual patient management decisions.

- The modified device includes data on preanalytical variables for serum, EDTA plasma, heparinized plasma and EDTA whole blood.

Performance Characteristics:

FEATURE	Nichols Advantage® Bio-Intact PTH (1-84) Immunoassay (K013992)	Bio-Intact PTH (1-84) Assay (K033302)*		Bio-Intact PTH (1-84) Assay (Modified)	
Precision within Run	Not greater than 4% at dose greater than 5 pg/mL	Within Run	Not greater than 6% at a dose greater than 5 pg/mL	Within Run	Not greater than 6% at a dose greater than 5 pg/mL
Precision Total	Not greater than 9.5% at dose greater than 34 pg/mL	Total	Not greater than 11% at a dose greater than 5 pg/mL	Total	Not greater than 11% at a dose greater than 5 pg/mL

*K033302 was submitted October 14, 2003 and is under review.

Method Comparison 1 – Serum Analysis Nichols Advantage Intact PTH Assay Vs. Bio-Intact PTH (1-84) Assay

FEATURE	Nichols Advantage® Bio-Intact PTH (1-84) Immunoassay (K013992)	Bio-Intact PTH (1-84) Assay (Modified)
Sample Size:	305	305
Range of Results:	Nichols Advantage Intact PTH Assay: 5.0 to 1387 pg/mL Nichols Advantage Bio-Intact PTH (1-84) Assay: 3.0 to 746 pg/mL	Nichols Advantage Intact PTH Assay: 5.0 to 1387 pg/mL Nichols Advantage Bio-Intact PTH (1-84) Assay: 3.0 to 746 pg/mL
Passing Bablok Regression Equation:	$y = 0.66x - 0.6$	$y = 0.66x - 0.6$
Least Squares Linear Regression Equation:	$y = 0.60x + 4.2$	$y = 0.60x + 4.2$
Pearson's Correlation Coefficient (r):	0.97	0.97

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Method Comparison 2 – Renal Dialysis Samples Nichols Advantage Intact PTH Assay Vs. Bio-Intact PTH (1-84) Assay

FEATURE	Nichols Advantage® Bio-Intact PTH (1-84) Immunoassay (K013992)	Bio-Intact PTH (1-84) Assay (Modified)
ample Size:	N/A	3187

Range of .esults:	N/A	Nichols Advantage Intact PTH Assay: 7 - 1797pg/mL Nichols Advantage Bio-Intact PTH (1-84) Assay 4-998
Least Squares Linear Regression Equation:	N/A	Y = 0.52 x + 1.3
Pearson's Correlation Coefficient (r):	N/A	0.97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 2 2004

Mr. Robert L. Schmidt
Director of Quality
Nichols Institute Diagnostics
1311 Calle Batido
San Clemente, CA 92673

Re: k033727
Trade/Device Name: Nichols Advantage® Bio-Intact PTH (1-84) Immunoassay
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid hormone test system
Regulatory Class: Class II
Product Code: CEW
Dated: March 18, 2004
Received: March 19, 2004

Dear Mr. Schmidt:

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

) **INDICATIONS FOR USE STATEMENT**

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510(k) Number (if known): K033727

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

Indications For Use:

The Nichols Advantage® Bio-Intact PTH (1-84) Immunoassay is intended for use with the Nichols Advantage® Specialty System to measure the levels of parathyroid hormone in serum, EDTA plasma and heparinized 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. Measurements of parathyroid hormone levels with the Bio-Intact PTH (1-84) Immunoassay are also used as an aid in monitoring therapeutic intervention of secondary hyperparathyroidism that frequently occurs in chronic kidney disease. Assay results should be used in conjunction with other clinical data to assist the clinician in making individual patient management decisions.

Prescription Use ✓ OR Over-The-Counter Use

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033727