11.0 510(k) 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: March 25, 2004

2. **Device Name:**

Trade/Proprietary Name:	Nichols Advantage® Chemiluminescence Intact Parathyroid Hormone
Common Name:	Radioimmunoassay, Parathyroid Hormone
Classification Name:	Parathyroid hormone test system

3. **Classification:** Class II
Regulation Number: 862.1545
Product Code: CEW, Clinical Chemistry

Predicate Device: Nichols Advantage Chemiluminescence Intact Parathyroid Hormone

4. **Device Description:**
The Nichols Advantage Intact PTH assay contains sufficient reagents for 100 tests. The assay is a two-site chemiluminometric assay specific for Intact PTH.

5. **Indications for Use:**
"The Nichols Advantage® Chemiluminescence Intact Parathyroid Hormone Immunoassay is intended for use with the Nichols Advantage® Specialty System for the quantitative determination of intact 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 intact parathyroid hormone levels 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:**

- Heparinized plasma was added to the specimen matrix for Intact PTH testing.
- Use of 6 different blood collection tubes was compared for similarities and differences for Intact PTH testing, and results of comparative testing yield essentially equivalent results.
- Specimen stabilities have been included in the new labeling for EDTA plasma, Heparinized plasma, and serum testing.
- New labeling and scientific references supporting use of Intact PTH testing in patients with chronic kidney diseases were added.

7. **Similarities:**

- There is no change in technology from the original device cleared under K962598.

8. **Additional Performance Characteristics**

- Crossreactivity to human PTH 7-84 was determined to be equimolar in the assay.
- Crossreactivity to human PTHrP 1-40 was determined to not cross react in the assay.

Conclusions: The device with modified labeling is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 8 2004

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

Re: k040813
Trade/Device Name: Nichols Advantage Chemiluminescence Intact Parathyroid Hormone
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid hormone test system
Regulatory Class: Class II
Product Code: CEW
Dated: March 20, 2004
Received: March 30, 2004

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

Indications for Use

510(k) Number (if known): K040813

Device Name: Nichols Advantage Chemiluminescence Intact Parathyroid Hormone

Indications For Use:

The Nichols Advantage® Chemiluminescence Intact Parathyroid Hormone Immunoassay is intended for use with the Nichols Advantage® Specialty System for the quantitative determination of intact parathyroid hormone in human EDTA plasma, heparinized plasma and serum. 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 intact parathyroid hormone levels 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 ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040813