K972495



OCT 10 1997

**510(k) Summary of Safety and Effectiveness**
**Information Upon Which an Equivalence Determination Could Be Made**
**October 1, 1997**

| | |
|---|---|
| Device Name: | AccuMeter® Theophylline Test |
| Common Name: | Theophylline Test System |
| Intended Use: | The ChemTrak AccuMeter® Theophylline Test provides a rapid, noninstrumented enzyme immunochromatographic method for *in vitro* quantitative measurement of Theophylline concentrations in ambulatory patients using fingerstick whole blood, heparinized venous whole blood or serum. This test has not been validated for use with blood from neonates. |
| Device Description: | The AccuMeter Theophylline Test is a rapid immunoassay for the quantitative detection of theophylline, using HRP labeled anti-theophylline antibodies and immobilized monoclonal anti-theophylline antibodies. The immunospecific signal is measured by the height of the enzyme label along the test strip. |
| Device Class: | Class II |
| Classification Panel: | Clinical Toxicology Test Systems |
| Facility Address: | ChemTrak, Inc.<br>929 East Arques Avenue<br>Sunnyvale, CA 94086-4520 |
| Contact Name: | SubbaRao Gunupudi, Ph.D.<br>Vice President Research & Development |
| Telephone: | (408) 773-8156 |
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| Alternate Contact: | Mark DeLaurentis<br>Clinical Research Manager |
| Telephone: | (408) 773-8156 |
| Fax: | (408) 773-1651 |
| Predicate Device Name: | TDx®/TDxFLX® Theophylline Monoclonal II<br>Abbott Laboratories, Abbott Park, IL.<br>510(k) Number: K932127 |

Sample collection and clinical evaluation of the AccuMeter Theophylline Test were performed at three independent clinical sites. IRB approval was obtained for the study protocol. TDx Theophylline testing was performed by a centralized reference laboratory.

Clinical studies were conducted at three sites. A minimum of 40 subjects receiving theophylline therapy were recruited from the patient population at each site. Five to ten theophylline-free subjects were also recruited. Informed consent was obtained from all subjects. The following subject demographic and medical information was collected: age; sex; theophylline dose. Site 1 also tested serum and heparinized whole blood on the AccuMeter. Serum was sent to the reference laboratory for TDx theophylline results.

**Accuracy**

The accuracy of the AccuMeter Theophylline Test has been demonstrated by correlation to Fluorescence Polarization Immunoassay (TDx) using fingerstick and serum specimens in separate studies.

Testing was performed on individuals receiving theophylline therapy at three independent clinical sites. The least-squares linear regression analysis of all sites combined is shown below (Table 1). In 30 out of 149 patients the results were less than the AccuMeter detection limit and were not included for regression analysis. Of the 454 cassettes run on patient samples, the Add Developer Window did not turn green in 6 cassettes and the Control Window did not turn purple in 1 cassette.

**Table 1:** Accuracy -- AccuMeter Compared to TDx Theophylline

| Y axis: | AccuMeter Fingerstick |
|---|---|
| X axis: | TDx |
| Slope | 1.05 |
| Intercept | -0.2 |
| Correlation Coefficient | 0.943 |
| Number of Observations | 102 |

The use of fingerstick whole blood, serum, and heparinized whole blood samples in the AccuMeter Theophylline Test was evaluated by parallel testing of 40 patients, by AccuMeter and TDx, at one clinical site. Testing was performed on individuals receiving theophylline therapy. Results of least-squares linear regression analysis are shown in Table 2.

**Table 2:** Comparison of AccuMeter Fingerstick, Serum and Whole Blood to TDx Theophylline

| Y Axis : | AccuMeter Fingerstick | AccuMeter Serum | AccuMeter Whole Blood |
|---|---|---|---|
| X Axis : | TDx | TDx | TDx |
| Slope | 1.06 | 1.03 | 0.99 |
| Intercept | 0.4 | 0.4 | 1.1 |
| Correlation Coefficient | 0.937 | 0.959 | 0.963 |
| Number of Observations | 40 | 39 | 39 |

**Precision**

Precision studies were conducted at three field sites. Two levels of controls were tested twice per day in duplicate over a period of 9 to 20 days. Results appear in Table 3.

**Table 3:** Within-Run and Total Precision of AccuMeter Theophylline Test

| | N* | Observed Mean µg/mL | SD µg/mL | % CV |
|---|---|---|---|---|
| **Study 1** | | | | |
| **Within Run** | | | | |
| Level 1 | 80 | 10.8 | 0.64 | 5.9 |
| Level 2 | 80 | 21.3 | 1.27 | 6.0 |
| **Total** | | | | |
| Level 1 | 80 | 10.8 | 0.82 | 7.6 |
| Level 2 | 80 | 21.3 | 1.43 | 6.7 |
| **Study 2** | | | | |
| **Within Run** | | | | |
| Level 1 | 80 | 10.4 | 0.80 | 7.7 |
| Level 2 | 80 | 22.6 | 1.34 | 6.0 |
| **Total** | | | | |
| Level 1 | 80 | 10.4 | 0.82 | 7.8 |
| Level 2 | 80 | 22.6 | 1.72 | 7.6 |
| **Study 3** | | | | |
| **Within Run** | | | | |
| Level 1 | 36 | 10.4 | 0.77 | 7.5 |
| Level 2 | 36 | 21.5 | 1.01 | 4.7 |
| **Total** | | | | |
| Level 1 | 36 | 10.4 | 1.11 | 10.7 |
| Level 2 | 36 | 21.5 | 1.81 | 8.4 |

*The Add Developer Window did not turn green in 8 AccuMeters and the Control Window did not turn purple in 1 AccuMeter.

**Sensitivity**

The sensitivity of the AccuMeter Theophylline assay is 5 µg/mL. Patient samples not containing theophylline may give results in the range 0 – 4.6 ug/mL. Patients whose blood gives a reading of <5 ug/mL should be reanalyzed by another method.

**Recovery**

Recovery for the AccuMeter Theophylline Test was determined by spiking theophylline into whole blood at five different concentrations (Table 4).

**Table 4:** Recovery of Theophylline in Whole Blood

| Concentration µg/mL | N | Mean µg/mL | Recovery (%) |
|---|---|---|---|
| 8.3 | 10 | 8.2 | 99.2 |
| 12.5 | 10 | 12.6 | 100.7 |
| 16.6 | 10 | 17.3 | 104.2 |
| 20.7 | 10 | 22.5 | 108.7 |
| 24.8 | 10 | 25.7 | 103.8 |

Substantial equivalence has been demonstrated between the AccuMeter Theophylline Test and the Abbott TDx®/TDxFLX® Theophylline Monoclonal II Assay. The characteristics of the AccuMeter Theophylline Test and TDx Theophylline Monoclonal II Assay (TDx) are summarized in Table 5.

**Table 5:** Comparison of the AccuMeter Theophylline Test to the TDx Theophylline Monoclonal II Assay (Predicate Device)

| **Characteristic Compared** | **AccuMeter Theophylline (Test Method)** | **TDx Theophylline Monoclonal II (Predicate Device)** |
|---|---|---|
| Intended Use | ". . .provides a rapid, noninstrumented enzyme immunochromatographic method for *in vitro* quantitative measurement of theophylline concentrations in ambulatory patients using fingerstick whole blood, heparinized venous whole blood or serum." | " . . . is a reagent system for the quantitative measurement of theophylline in serum or plasma." |
| Analyte | Theophylline | Theophylline |
| Methodology | Noninstrumented, Enzyme Immunochroma-tographic | Fluorescence Polarization Immunoassay |
| Test Sample | Whole Blood or Serum<br>No Pretreatment | Serum or Plasma<br>No Pretreatment |
| Test Components | Single-use Cassette<br>Color Developer | Reagent Kit<br>Calibrator Kit<br>Fluorometer |
| Assay Range | 5-30 µg/mL | 0.82-40 µg/mL |
| Method of Detection | Visual<br>Quantitative | Spectrophotometric<br>Quantitative |
| Test Storage | Refrigerated | Refrigerated |

The regression data demonstrates substantial equivalence, as well as the safety and effectiveness, of the AccuMeter Theophylline Test to the TDx Theophylline Assay.

Prepared and Submitted October 1, 1997
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 10 1997

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ChemTrak, Inc.
929 East Arques Avenue
Sunnyvale, California 94086

Re: K972495
Trade Name: AccuMeter® Theophylline Test
Regulatory Class: II
Product Code: KLS
Dated: September 15, 1997
Received: September 16, 1997

Dear Dr. Gunupudi:

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 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 requirement, 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

510(k) Number (if known): K972495

Device Name: AccuMeter® Theophylline Test

Indications For Use:

The AccuMeter® Theophylline Test is a rapid, noninstrumented enzyme immunochromatographic method for the in vitro quantitative measurement of theophylline concentrations in ambulatory patients using fingerstick whole blood, heparinized venous whole blood or serum. This test has not been validated for use with blood from neonates.

(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 K972495

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)