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MAR - 8 2004

Summary of 510(k) Safety and Effectiveness Information
Vitalab Uric Acid Reagent K040467

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitted by:

Clinical Data, Inc.
1075 West Lambert Road, Building D
Brea, California 92861

Contact Person: Wynn Stocking
Regulatory Affairs Manager

Date Submitted: February 4, 2004

Device Names:

Proprietary name: Vitalab Uric Acid Reagent

Common name: Uric acid reagent

Classification Name: Acid, uric, uricase (colorimetric)

Device Description:

The Vitalab Uric Acid Reagent is a two-part reagent for use with the Vitalab Selectra Analyzer. This reagent determines uric acid through enzymatic oxidation by uricase linked to a Trinder indicator reaction utilizing N-ethyl-N-(hydroxy-3-sulfopropyl)-toluidine (TOOS) and 4-aminoantipyrine.

Intended Use:

The Vitalab Uric Acid Reagent Kit is intended for use with the Vitalab Selectra Analyzer as a system for the quantitative determination of uric acid in serum and plasma. Uric acid results may be used for the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

Predicate Device:

Vitalab Uric Acid Reagent Kit is substantially equivalent to the Roche Uric Acid Plus Reagent, product no. 1661850, which is currently marketed by Roche Diagnostics Corp. of Indianapolis, IN.

Summary of Performance Data:

Usable Range: The linear range of the Vitalab Uric Acid Reagent is from 0.1 to at least 25 mg/dL, as shown by the recovery of linearity standards that span the linear range. Least squares regression statistics, forced through the origin, compare recoveries to standard concentrations.

(Vitalab Recoveries) = 0 mg/dL + 1.027 x (Concentration), $r = 0.9999$, $s_{y.x} = 0.12$ mg/dL, $n = 40$

Detection Limit: Normal saline was assayed thirty times in a single analytical run. The mean and standard deviation of the results are both 0.0 mg/dL. The minimum detection limit, calculated as the mean plus two standard deviations of the recovery values, is rounded up to 0.1 mg/dL, which is the round-off error of the assay.

Precision: Precision is demonstrated by the replicate assay of commercially available control serum. Precision statistics, calculated analogous to the method described in NCCLS Guideline EP3-T, are shown below.

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	60	2.5	0.02	0.7%	0.04	1.6%
Serum 2	60	6.8	0.04	0.7%	0.09	1.4%
Serum 3	60	11.1	0.07	0.6%	0.13	1.2%

Correlation: Sixty serum specimens ranging from 3.6 to 10.2 mg/dL uric acid and 60 heparinized plasma specimens ranging from 2.1 to 10.6 mg/dL uric acid were collected from adult patients and were assayed for uric acid using the Vitalab Selectra E Analyzer and another commercially available method. Results were compared by Deming regression and the following statistics were obtained.

Selectra = -0.05 mg/dL + 0.995 x Competitive Reagent
$s_{y.x}$ = 0.08 mg/dL n = 120 range = 2.1 - 10.6 mg/dL

Stability: The 14 day onboard reagent stability and 7 day calibration stability claims are documented through the assay of serum controls over the claimed periods. In all cases, statistical estimates of total imprecision are less than 0.2 mg/dL.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR - 8 2004

Clinical Data, Inc.
c/o: Mr. Ned E. Devine, Jr.
Entela, Inc
3033 Madison Avenue, SE
Grand Rapids, MI 49548

Re: k040467
Trade/Device Name: Vitalab Uric Acid Reagent
Regulation Number: 21 CFR 862.1775
Regulation Name: Uric acid test system
Regulatory Class: Class I
Product Code: KNK
Dated: February 24, 2004
Received: February 24, 2004

Dear Mr. Devine:

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

510(k) Number (if known): K040467

Device Name: Vitalab Uric Acid Reagent

Indications for Use:

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✓ prescription use

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

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040467