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MAR 1 1 2004

K040534

Summary of 510(k) Safety and Effectiveness Information
Vitalab α-Amylase Reagent

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: January 21, 2003

Device Names:

Proprietary name: Vitalab Amylase Reagent

Common name: Amylase reagent

Classification Name: Catalytic methods, amylase

Device Description:

The Vitalab α-Amylase Reagent is a single-part reagent for use with the Vitalab Selectra Analyzer. This reagent determines amylase through the cleavage of 2-chloro-4-nitrophenyl-α-D-maltotrioside (CNP-α-G_3) to produce 2-chloro-4-nitrophenol.

Intended Use:

The Vitalab α-Amylase Reagent Kit is intended for use with the Vitalab Selectra Analyzer for the quantitative determination of α-amylase in serum and plasma. Amylase results may be used for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

Predicate Device:

Roche α-Amylase EPS ver.2 Reagent, product no. 03183742, which is currently marketed by Roche Diagnostics Corp. of Indianapolis, IN

Summary of Performance Data:

Usable Range: The linear range of the Vitalab α-Amylase Reagent is 5 to 1,600 U/L using the default sample volume and 1,200 to 3,200 U/L using the reduced sample volume in rerun mode. The recoveries of linearity related solutions that span the linear range are compared to dilution factors using least squares regression, which is forced through the origin.

Default sample volume
(Vitalab Recoveries) = 0 U/L + 131 x (Dilution Factor), $r = 0.9999$, $s_{y.x} = 7.2$ U/L, $n = 28$

Rerun sample volume
(Vitalab Recoveries) = 0 U/L + 133 x (Dilution Factor), $r = 0.9999$, $s_{y.x} = 17$ U/L, $n = 60$

Detection Limit: The detection limit is shown through the repetitive assay of normal saline. The observed mean and standard deviation of a 30 replicate run are 0.3 and 1.8 U/L respectively. The detection limit, calculated as the mean plus two standard deviations of the recovery values, is 0.4 U/L.

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

Instrument Range			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Default						
Serum 1	60	98	1.0	1.0%	1.5	1.5%
Serum 2	60	565	3.6	0.6%	5.0	0.9%
Serum 3	60	1,034	7.0	0.7%	9.7	0.9%
Rerun						
Serum 1	60	1,961	17	0.9%	25	1.3%
Serum 2	60	2,517	26	1.0%	41	1.6%
Serum 3	60	3,002	40	1.3%	50	1.7%

Correlation: Mixed serum and plasma specimens, collected from adult patients, were assayed for α-amylase using the Vitalab Selectra E Analyzer and another commercially available method. Results were compared by Deming regression and the following statistics were obtained.

Selectra = -6 U/L + 1.086 x Competitive Reagent
$s_{y.x} = 4.0$ U/L $n = 120$ range = 26 - 1049 U/L

Stability: The 14 day onboard reagent stability claim is documented through the assay of serum controls over the claimed period. The statistical estimates of total imprecision are less than 2 U/L or 1.2% for all controls.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 1 2004

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

Re: k040534
Trade/Device Name: Vitalab α-Amylase Reagent
Regulation Number: 21 CFR 862.1070
Regulation Name: Amylase test system
Regulatory Class: Class II
Product Code: JFJ
Dated: March 2, 2004
Received: March 2, 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): K040534

Device Name: Vitalab α-Amylase Reagent

Indications for Use:

The Vitalab α-Amylase Reagent Kit is intended for use with the Vitalab Selectra Analyzer as a system for the quantitative determination of α-amylase in serum and plasma. Amylase results may be used for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040534

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

(Optional Format 1-2-96)