K034000

MAR 1 0 2004

Clinical Data

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Summary of 510(k) Safety and Effectiveness Information

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.

The Vitalab Triglycerides Reagent, the Vitalab Calibrator and the Vitalab Selectra Analyzer are used as a system for the quantitative analysis of triglycerides in serum and plasma. Triglycerides results may be used for the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction and other diseases involving lipid metabolism, various endocrine disorders, or for assessing of the risk of developing cardiovascular diseases. The Vitalab Triglycerides Reagent determines triglycerides using the lipase/GPO enzymatic assay procedure coupled to a Trinder indicator reaction. The resulting increase in absorbance at 505 nm is proportional to the triglycerides concentration of the sample.

The Vitalab Triglycerides Reagent Kit and Vitalab Serum Calibrator are substantially equivalent to the Beckman Triglycerides Reagent Kit, product no. 445850 and the Synchron Multi-Calibrator, product no. 442600, which are marketed by Beckman Coulter, Inc. of Brea, CA.

The effectiveness of Vitalab Triglycerides Reagent on the Vitalab Selectra is shown in the following studies.

The recovery of triglycerides using the Vitalab Triglycerides Reagent is linear from 5 to at least 900 mg/dL, as shown by the recovery of linearity standards that span from 0 mg/dL to 930 mg/dL triglycerides. Regression statistics, which are forced through the origin, compare standard recoveries to dilution factors. These statistics are shown below.

(Vitalab Recoveries) = 1.164 x (Dilution Factor), r = 0.9999, sy.x = 3.7 mg/dL, n = 44

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.

Precision of Triglycerides Recoveries in mg/dL

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	60	69	0.6	0.9%	1.1	1.6%
Serum 2	60	291	1.6	0.6%	4.4	1.5%
Serum 3	60	624	3.5	0.6%	11.3	1.8%

Fifty nine serum specimens ranging from 56 to 519 mg/dL triglycerides and 60 heparinized plasma specimens ranging from 28 to 701 mg/dL triglycerides were collected from adult patients and were assayed for triglycerides using the Vitalab Selectra Analyzer and another commercially available method. Results were compared by Deming regression and the following statistics were obtained.

Serum Correlation

	Value	95% Confidence Interval
Intercept	-4.0 mg/dL	-6.9 to 1.16 mg/dL
Slope	1.071	1.059 to 1.083
sy.x:	3.6 mg/dL	

Plasma Correlation

	Value	95% Confidence Interval
Intercept	-0.2 mg/dL	-2.4 to 2.1 mg/dL
Slope	1.068	1.057 to 1.079
sy.x:	3.6 mg/dL	

Where x = Competitive Reagent Results
y = Selectra Results

The claimed detection limit is documented through the repetitive assay of normal saline. The mean and standard deviation of a 30 replicate within run precision study are both 0 mg/dL. The minimum detection limit, calculated as the mean plus two standard deviations of the recovery values, is rounded up to 1 mg/dL, which is the round-off error of the assay.

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, the total imprecision of triglycerides recoveries over the test periods are less than 2 mg/dL.

The three day reconstituted stability claim for the calibrator is shown by assaying calibrators of increasing ages. The observed change in triglycerides concentration over three days was less than 5% and statistically insignificant.

Wynn Stocking
Manager of Regulatory Affairs
Clinical Data, Brea CA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 0 2004

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

Re: k034000
Trade/Device Name: Vitalab Triglycerides Reagent and Vitalab Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX; CDT
Dated: February 23, 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): K034000

Device Name: Vitalab Triglycerides Reagent and Vitalab Calibrator

Indications for Use:

The Vitalab Triglycerides Reagent, the Vitalab Calibrator and the Vitalab Selectra Analyzer are intended for use as a system for the quantitative determination of triglycerides in serum and plasma. Triglycerides results may be used for the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction and other diseases involving lipid metabolism, various endocrine disorders, or for assessing of the risk of developing cardiovascular diseases.

(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) K034000

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)