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510(k) Summary

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Device Name: Colorimetric Method, Gamma Glutamyltransferase

Predicate Device: Gamma Glutamyl Transferase Procedure, Sigma Diagnostics, St. Louis, Missouri.

Device Description: The method is based on the reaction wherein gamyl glutamyltransferase catalyzes the transfer of the glutamyl group from L-g-glutamyl-3-carboxy-4-nitroanilide to glycylglycine with the formation of g-glutamylglycylglycine and 5-amino-2-nitrobenzoate. The rate of increase of 5-amino-2-nitrobenzene, which absorbs light at 405 nM, is proportional to the gamma glutamyltransferase activity in the sample.

Intended Use: For in-vitro diagnostic use. For the quantitative determination of gamma glutamyltransferase in serum.

Elevated serum gamma glutamyltransferase (GGT) is found in chronic alcoholism, diabetes, certain neurological disorders, and all forms of liver disease. It is more sensitive than alkaline phosphatase, the transaminases, and leucine aminopeptidase (LAP) in detecting obstructive jaundice, cholangitis, and cholecystitis; its rise occurs earlier than these other enzymes and persists longer. Moderate increases are seen with infectious hepatitis, and normal levels are seen in skeletal disease. Serum GGT levels can therefore be used to differentiate skeletal or hepatobiliary disease.

The intended use is the same as the predicate device.

Material comparison with predicate device:

	DMA	Sigma
L-g-Glutamyl-3-Carboxy-4-Nitroanilide	4.39 mmol/L	4.36 mmol/L
Glycylglycine	60 mmol/L	60 mmol/L
Preservative	yes	yes
Surfactant	yes	no
Buffer	no	yes
Stabilizer	no	yes
Fillers	no	yes

Non Clinical Test Comparison:

Linearity	to 2000 U/L
Precision	
Within-Run	(at approximately 12 U/L) C.V. of 4.6% (at approximately 51 U/L) C.V. of 2.5% (at approximately 1100 U/L) C.V. of 3.1% (at approximatley 1870 U/L) C.V. of 1.7%
Run-to-Run	(at approximately 12 U/L) C.V. of 7.3% (at approximately 50 U/L) C.V. of 3.7% (at approximately 1090 U/L) C.V. of 1.4% (at approximatley 1880 U/L) C.V. of 0.9%
Shelf-Life	19 months at 2°-8°C
Sensitivity (0.001A)	4.0 U/L
(Analytical)	3.8 U/L
Interrferences	
Bilirubin	no interference to 17.8 mg/dL bilirubin
Hemoglobin	(at approximately 82 U/L GGT) no interference up to 321 mg/dL hemoglobin
Lipemia	(at approximately 25 U/L GGT) no interference up to 877 mg/dL triglyceride (at approximately 80 U/L GGT) no interference up to 482 mg/dL triglyceride
Expected Values	9-55 U/L

Conclusion: Based upon the comparative testing with the predicate device consisting of the principle of the test, comparison of reagents, and performance characteristics of stability, linearity, expected values, precision, sensitivity and correlation, all found in the body of the submission, it is concluded by the submitter that the proposed device is substantially equivalent to the predicate device.