

SUMMARY OF SAFETY AND EFFECTIVENESS

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Product Trade Name: CDM™

Common Name: Clinical Data Management System

Classification Name: Calculator/Data Processing Module, for Clinical use, 75 JQP

To establish substantial equivalence to an existing predicate device, the CDM has been compared to the Hewlett-Packard 3392A Reporting Integrator (K833113). A review of the intended use of each system shows them to be essentially the same. The intended use of the CDM is stated as: *A software package and instrument interface that is used for quantitative analyses of high performance liquid chromatography (HPLC) test kits.* The intended use of the 3392A Reporting Integrator is stated as: *The 3392A is a multipurpose instrument that may be used for qualitative or quantitative analyses in many applications (see Appendix I).*

A comparison of the technical features of the CDM and 3392A show the devices to be very similar. The CDM makes use of a 486 IBM compatible computer and a separate communications interface. The system is described in detail in Appendix C. In brief, the CDM accepts signals from a detector, integrates the chromatograms, identifies reference peaks and performs calculations of percent area. In addition, the CDM can control pumps and an automated sampler and store quality control data.

The predicate device, the H-P 3392A, is a CPU device with communication capability. Again, the 3392A accepts signals from a detector, integrates the chromatograms, identifies reference peaks and performs calculations of percent area. In addition, the 3392A can control an automated sampler. A complete comparison of the CDM and the predicate 3392A is summarized in Appendix D.

An analytical comparison of the CDM and the Shimadzu CR501 was done for each of the following five tests: 1) HVA by HPLC 2) Urinary Metanephrines by HPLC, 3) VMA by HPLC, 4) Plasma Catecholamines by HPLC, 5) Benzodiazepines & Tricyclic Antidepressants by HPLC.

First, using the HVA by HPLC test, analytical sensitivity was: CR501 SD 0.018, CV 3.6%; CDM SD 0.020 CV 4.0%. Accuracy using HVA by HPLC test yielded a correlation coefficient of 0.9999, a y-intercept of 0.011, and a slope of 0.994. The HVA by HPLC test results for analytical sensitivity and method comparison given by the Clinical Data Management (CDM) System are comparable to those obtained using the CR501 integrator.

Second, using the urinary metanephrines by HPLC test for analytical sensitivity yielded the following: Metanephrine CR501 SD 0.986, CV 6.8%; Metanephrine CDM SD 0.796, CV 5.5%; Normetanephrine CR501 SD 1.118, CV 6.0%; Normetanephrine CDM SD 1.345 CV 7.6%; 3-Methoxytyramine CR501 SD 0.750, CV 9.6%; 3-Methoxytyramine CDM SD 0.546 CV 7.8%. CDM accuracy using the urinary metanephrines by HPLC was: Metanephrine CDM yielded a correlation coefficient of 0.9999, a y-intercept of -1.074, and a slope of 1.017; Normetanephrine CDM yielded a correlation coefficient of 0.9999, a y-intercept of -2.867, and a slope of 1.023; 3-Methoxytyramine CDM yielded a correlation coefficient of 0.9999, a y-intercept of -0.552, and a slope of 0.999. The urinary metanephrines by HPLC test results for sensitivity and method comparison given by the Clinical Data Management (CDM) System are comparable to those using the CR501 integrator.

Third, using the VMA by HPLC test, analytical sensitivity was: CR501 VMA SD 0.010, CV 1.9%; CDM VMA SD 0.010, CV 1.9%. CDM VMA yielded a correlation coefficient of 0.9998, a y-intercept of -0.002, and a slope of 0.994. The VMA by HPLC results for analytical sensitivity and method comparison given by the Clinical Data Management (CDM) System are comparable to those using the CR501 integrator.

Fourth, using the Plasma Catecholamines by HPLC test, analytical sensitivity was: Epinephrine CR501 SD 2.72, CV 18%; Epinephrine CDM SD 1.32, CV 13%; Norepinephrine CR501 SD 5.04, CV 14%; Norepinephrine CDM SD 3.74, CV 12%. Epinephrine CDM yielded a correlation coefficient 0.9998, a y-intercept -2.90, and a slope 0.979 and Norepinephrine CDM yielded a correlation coefficient 0.9999, a y-intercept -4.43, and a slope 1.003. The Plasma Catecholamines by HPLC test results for sensitivity and response comparison given by the Clinical Data Management (CDM) System are comparable to those using the CR501 integrator.

The fifth test used the benzodiazepines & tricyclic antidepressants by HPLC. Each of these tests measure multiple analytes. The following data represent the means of the sensitivity and accuracy results. Using the Benzodiazepine by HPLC test method analytical sensitivity was: a mean CR501 SD 1.64; a mean CR501 CV 6.44%; a mean CDM SD 1.59; a mean CDM CV 5.92%. Accuracy for the Benzodiazepine by HPLC test method was: a mean correlation coefficient of 0.9998, a mean y-intercept -0.156, and a mean slope 0.9982.

Using the tricyclic antidepressants by HPLC test method, analytical sensitivity was: CR501 a mean SD 1.37 a mean CV 5.23%; CDM a mean SD 1.24 and a mean CV 4.74%. Accuracy for the tricyclic antidepressants by HPLC test method was: a mean correlation coefficient of 0.9997, a mean y-intercept 4.25 and a mean slope 0.955.

Equivalence was shown between the Clinical Data Management (CDM) system and the CR501 integrator in testing the following: 1) HVA by HPLC 2) Urinary Metanephrines by HPLC, 3) VMA by HPLC, 4) Plasma Catecholamines by HPLC, 5) Benzodiazepines & Tricyclic Antidepressants by HPLC.