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510(k) Summary
Abbott AxSYM Free T_3

Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

The following information as presented in the Premarket Notification for AxSYM® Free T_3 constitutes data supporting a substantially equivalent determination.

AxSYM Free T_3 is a microparticle enzyme immunoassay for the quantitative determination of free T_3 in human serum or plasma (lithium heparin, sodium heparin, or dipotassium EDTA). AxSYM Free T_3 is calibrated with Abbott calibrators. Abbott controls are assayed for the verification of the accuracy and precision of the Abbott AxSYM System.

Substantial equivalence has been demonstrated between the Abbott AxSYM Free T_3 assay and the Ciba Corning Automated Chemiluminescence System (ACS) Free T_3 Immunoassay. The intended use of both assays is for the quantitative determination of free T_3. AxSYM Free T_3 can be performed with human serum or plasma (lithium heparin, sodium heparin, or dipotassium EDTA). However, ACS Free T_3 can be performed on human serum only. A correlation analysis between these two assays, using 745 specimens, yielded a correlation coefficient of 0.948, slope of 1.19, standard error of estimate of 0.775, and Y-axis intercept of -0.96 pg/mL. The AxSYM Free T_3 assay has a dynamic range of 1.1- 30.0 pg/mL, whereas the ACS Free T_3 assay has a dynamic range of 0.5- 20.0 pg/mL.

In conclusion, these data demonstrate that the AxSYM Free T_3 assay is safe and effective, and is substantially equivalent to the Ciba Corning Automated Chemiluminescence System (ACS) Free T_3 Immunoassay.

Prepared and Submitted September 20, 1996 by:

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