

K 963833

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**510(k) Summary  
Abbott IMx Free T<sub>3</sub>**

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**Summary of Safety and Effectiveness Information Supporting a  
Substantially Equivalent Determination**

The following information as presented in the Premarket Notification for IMx<sup>®</sup> Free T<sub>3</sub> constitutes data supporting a substantially equivalent determination.

IMx Free T<sub>3</sub> is a microparticle enzyme immunoassay for the quantitative determination of free T<sub>3</sub> in human serum or plasma (lithium heparin, sodium heparin, or dipotassium EDTA). IMx Free T<sub>3</sub> is calibrated with Abbott calibrators. Abbott controls are assayed for the verification of the accuracy and precision of the Abbott IMx Analyzer.

Substantial equivalence has been demonstrated between the Abbott IMx Free T<sub>3</sub> assay and the Ciba Corning Automated Chemiluminescence System (ACS) Free T<sub>3</sub> Immunoassay. The intended use of both assays is for the quantitative determination of free T<sub>3</sub>. IMx Free T<sub>3</sub> can be performed with human serum or plasma (lithium heparin, sodium heparin, or dipotassium EDTA). However, ACS Free T<sub>3</sub> can be performed on human serum only. A correlation analysis between these two assays, using 767 specimens, yielded a correlation coefficient of 0.942, slope of 1.14, standard error of estimate of 0.783, and Y-axis intercept of -0.47 pg/mL. The IMx Free T<sub>3</sub> assay has a dynamic range of 1.1- 30.0 pg/mL, whereas the ACS Free T<sub>3</sub> assay has a dynamic range of 0.5- 20.0 pg/mL.

In conclusion, these data demonstrate that the IMx Free T<sub>3</sub> assay is safe and effective, and is substantially equivalent to the Ciba Corning Automated Chemiluminescence System (ACS) Free T<sub>3</sub> Immunoassay.

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