Food and Drug Administration, HHS

§ 862.1115 Urinary bilirubin and its conjugates (nonquantitative) test system.

(a) Identification. A urinary bilirubin and its conjugates (nonquantitative) test system is a device intended to measure the levels of bilirubin conjugates in urine. Measurements of urinary bilirubin and its conjugates (nonquantitative) are used in the diagnosis and treatment of certain liver diseases.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in

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