§ 866.6020  
(b) **Classification.** Class II (special controls). Tumor markers must comply with the following special controls: (1) A guidance document entitled “Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications (510(k)s) to FDA,” and (2) voluntary assay performance standards issued by the National Committee on Clinical Laboratory Standards.


§ 866.6020  **Immunomagnetic circulating cancer cell selection and enumeration system.**

(a) **Identification.** An immunomagnetic circulating cancer cell selection and enumeration system is a device that consists of biological probes, fluorochromes, and other reagents; preservation and preparation devices; and a semiautomated analytical instrument to select and count circulating cancer cells in a prepared sample of whole blood. This device is intended for adjunctive use in monitoring or predicting cancer disease progression, response to therapy, and for the detection of recurrent disease.

(b) **Classification.** Class II (special controls). The special control for this device is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System.” See §866.1(e) for availability of this guidance document.

[82 FR 66005, Dec. 17, 1997]

§ 866.6030  **AFP-L3% immunological test system.**

(a) **Identification.** An AFP-L3% immunological test system is an in vitro device that consists of reagents and an automated instrument used to quantitatively measure, by immunochemical techniques, AFP and AFP-L3 subfraction in human serum. The device is intended for in vitro diagnostic use as an aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma, in conjunction with other laboratory findings, imaging studies, and clinical assessment.

(b) **Classification.** Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems.” See §866.1(e) for the availability of this guidance document.

[70 FR 57749, Oct. 4, 2005]

§ 866.6040  **Gene expression profiling test system for breast cancer prognosis.**

(a) **Identification.** A gene expression profiling test system for breast cancer prognosis is a device that measures the ribonucleic acid (RNA) expression level of multiple genes and combines this information to yield a signature (pattern or classifier or index) to aid in prognosis of previously diagnosed breast cancer.

(b) **Classification.** Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Gene Expression Profiling Test System for Breast Cancer Prognosis.” See §866.1(e) for the availability of this guidance document.

[72 FR 26291, May 9, 2007]