§ 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 fraction 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 for this device is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Ovarian Adnexal Mass Assessment Score Test System.” For the availability of this guidance document, see §866.1(e).

(c) Black box warning. Under section 520(e) of the Federal Food, Drug, and Cosmetic Act these devices are subject to the following restriction: A warning statement must be placed in a black box and must appear in all advertising, labeling, and promotional material for these devices. That warning statement must read:

PRECAUTION: The [test name] should not be used without an independent clinical/radiological evaluation and is not intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of the [test name] carries the risk of unnecessary testing, surgery, and/or delayed diagnosis.